

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: GENERIC  
PHARMACEUTICALS PRICING  
ANTITRUST LITIGATION**

***IN RE: CLOBETASOL CASES***

***IN RE: CLOMIPRAMINE CASES***

**THIS DOCUMENT APPLIES TO:  
*EPP BELLWETHER ACTIONS***

**MDL NO. 2724  
16-md-2724**

**EPP CASE: 16-CB-27242**

**EPP CASE: 16-CM-27242**

**OPINION**

**Rufe, J.**

**December 3, 2024**

This multidistrict antitrust litigation concerns alleged price-fixing schemes involving numerous generic drugs and generic drug manufacturers. The Court has selected as initial bellwether cases proposed class actions brought by End-Payer Plaintiffs (“EPPs”) and Direct Purchaser Plaintiffs (“DPPs”) as to two generic drugs, clomipramine and clobetasol. This Opinion considers motions to exclude expert testimony relevant to the EPPs’ motion for class certification. Defendants have moved to exclude the opinions of certain of EPPs’ experts: Dr. James T. McClave, Ms. Laura R. Craft, Mr. Eric J. Miller, and Dr. Russell L. Lamb. EPPs have moved to exclude defense experts Dr. James W. Hughes, Dr. Erin E. Trish, Dr. Laura E. Happe, and Dr. Richard J. Gilbert. The Court has considered each expert’s report, the parties’ briefs, and the evidence and argument presented during several days of hearings.

## I. BACKGROUND

The Court provides the background relevant to this Opinion.<sup>1</sup> EPPs include employee welfare benefits funds, labor unions, private insurers, and municipalities, as well as individual plaintiffs. They allege either that they indirectly purchased generic pharmaceuticals manufactured by Defendants or that they provided reimbursements for some or all of the purchase price for generic clobetasol and clomipramine prescriptions. Clobetasol is a potent topical corticosteroid that is prescribed for severe inflammatory skin issues. The drug comes in five formulations: cream, emollient cream, ointment, solution, and gel.<sup>2</sup> Clomipramine is an antidepressant pill used to treat certain mental health issues, such as obsessive-compulsive disorder.<sup>3</sup>

EPPs contend that Defendants, the manufacturers of generic clomipramine and clobetasol, engaged in anticompetitive conduct that was part of a larger conspiracy or series of conspiracies involving many generic pharmaceutical manufacturers and many generic pharmaceuticals to fix, maintain, and stabilize prices and rig bids of generic drugs through market and consumer allocations of generic pharmaceutical products.<sup>4</sup>

### A. Clobetasol and Clomipramine Bellwether Cases

The Court ordered the parties to begin proceedings to bring to trial, on parallel tracks, the EPP and DPP proposed class-action complaints as to clobetasol and clomipramine as bellwether

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<sup>1</sup> A fuller discussion of the allegations in the MDL may be found in the Court's Opinions of October 16, 2018, and February 15, 2019. *See In re Generic Pharms. Pricing Antitrust Litig.*, 338 F. Supp. 3d 404, 411–34 (E.D. Pa. 2018); *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 820–27 (E.D. Pa. 2019).

<sup>2</sup> Consolidated Am. Class Action Compl. [Clobetasol], No. 16-CB-27242 [Doc. No. 167] ¶ 2.

<sup>3</sup> Consolidated Am. Class Action Compl. [Clomipramine], No. 16-CM-27242 [Doc. No. 126] ¶ 2.

<sup>4</sup> *See* Consolidated Am. Compl. [Clobetasol] [Doc. No. 167] ¶ 1; Consolidated Am. Class Action Compl. [Clomipramine] [Doc. No. 126] ¶ 1.

cases.<sup>5</sup> Pertinent to this Opinion, EPPs have moved for class certification in the clomipramine and clobetasol cases, which Defendants oppose. EPPs seek to certify the following three classes under Federal Rule of Civil Procedure 23(a) and (b)(3) with regard to their claims under certain state and territory (1) antitrust laws, (2) consumer protection laws, and (3) common laws of unjust enrichment:

For the Clomipramine case:

Antitrust Damages Class:

All Third-Party Payers who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Defendants' generic Clomipramine products (generic clomipramine hydrochloride 25, 50, or 75 mg capsules) purchased in the Antitrust Damages Jurisdictions at retail or via mail-order, for personal use by their members, enrollees or beneficiaries and not for resale, from August 1, 2013 through December 31, 2018.

Consumer Protection and Unfair Competition Damages Class:

All Third-Party Payers who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Defendants' generic Clomipramine products (generic clomipramine hydrochloride 25, 50, or 75 mg capsules) purchased in the Consumer Protection Damages Jurisdictions at retail or via mail-order, for personal use by their members, enrollees or beneficiaries and not for resale, from August 1, 2013 through December 31, 2018.

Unjust Enrichment Class:

All Third-Party Payers who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Defendants' generic Clomipramine products (generic clomipramine hydrochloride 25, 50, or 75 mg capsules) purchased in the Unjust Enrichment Jurisdictions at retail or via mail-order, for personal use by their members, enrollees or beneficiaries and not for resale, from August 1, 2013 through December 31, 2018.

Exclusions

Excluded from each of the three Classes are: (a) Defendants, their subsidiaries, and affiliates; (b) all federal governmental entities; (c) all state governmental entities; and (d) Third-Party Payers for purchases made pursuant to any Medicaid plan, whether fee-for-service or Managed Medicaid.

For the avoidance of doubt, the Classes do not include: (a) natural person consumers; (b) Pharmacy Benefit Managers [("PBMs")]; or (c) purchases made

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<sup>5</sup> Pretrial Order No. 132 [MDL Doc. No. 1443].

other than via retail or mail order. The Classes do include: cities, towns, municipalities, or counties with self-funded prescription drug plans.<sup>6</sup>

For the Clobetasol case:

Antitrust Damages Class:

All Third-Party Payers who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Defendants' generic Clobetasol products (generic clobetasol propionate cream, emollient cream, ointment, solution and gel) purchased in the Antitrust Damages Jurisdictions at retail or via mail-order, for personal use by their members, enrollees or beneficiaries and not for resale, from September 1, 2014 through December 31, 2018.

Consumer Protection and Unfair Competition Damages Class:

All Third-Party Payers who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Defendants' generic Clobetasol products (generic clobetasol propionate cream, emollient cream, ointment, solution and gel) purchased in the Consumer Protection Damages Jurisdictions at retail or via mail-order, for personal use by their members, enrollees or beneficiaries and not for resale, from September 1, 2014 through December 31, 2018.

Unjust Enrichment Class:

All Third-Party Payers who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Defendants' generic Clobetasol products (generic clobetasol propionate cream, emollient cream, ointment, solution and gel) purchased in the Unjust Enrichment Jurisdictions at retail or via mail-order, for personal use by their members, enrollees or beneficiaries and not for resale, from September 1, 2014 through December 31, 2018.

Exclusions

Excluded from each of the three Classes are: (a) Defendants, their subsidiaries, and affiliates; (b) all federal governmental entities; (c) all state governmental entities; and (d) Third-Party Payers for purchases made pursuant to any Medicaid plan, whether fee-for-service or Managed Medicaid.

For the avoidance of doubt, the Classes do not include: (a) natural person consumers; (b) Pharmacy Benefit Managers; or (c) purchases made other than via retail or mail order. The Classes do include: cities, towns, municipalities, or counties with self-funded prescription drug plans.<sup>7</sup>

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<sup>6</sup> EPPs' Mot. Class Cert. [Clomipramine], No. 16-CM-27242 [Doc. No. 180] at 1–3 (footnotes and emphasis omitted).

<sup>7</sup> EPPs' Mot. Class Cert. [Clobetasol]236, No. 16-CB-27242 [Doc. No. 236] at 1–3 (footnotes and emphasis omitted).

EPPs and Defendants have proffered the opinions of a number of experts in the fields of econometrics and health care that bear on the question of whether the proposed classes should be certified. Accordingly, both parties have filed several motions to exclude the opinions of several experts under Rule 702 of the Rules of Evidence. The Court held hearings on these *Daubert* motions<sup>8</sup> on a selection of these experts on September 24-26, 2024, and October 8, 2024. EPPs and Defendants presented oral argument as to the *Daubert* motions in this opinion on October 10, 2024. During the hearings on September 24-26<sup>th</sup>, the parties presented evidence and argument regarding Dr. McClave, Ms. Craft, Mr. Miller, and Dr. Lamb (EPPs' witnesses) and Dr. Hughes, Dr. Trish, and Dr. Happe (Defendants' witnesses).

## II. LEGAL STANDARD

Federal Rule of Evidence 702 provides that:

[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.<sup>9</sup>

The focus of the Court's inquiry must be on the expert's methods, not the expert's conclusions. The Third Circuit has interpreted Rule 702 as setting forth three requirements: (1) the expert must be qualified; (2) the expert must testify about matters requiring scientific,

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<sup>8</sup> See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993).

<sup>9</sup> Fed. R. Evid. 702.

technical, or specialized knowledge; and (3) the expert’s testimony must assist the trier of fact.<sup>10</sup>

“The proponent of the expert testimony bears the burden to show by a preponderance of the evidence that their expert’s opinion is reliable.”<sup>11</sup> District courts have “broad discretion in determining the admissibility of evidence, and ‘considerable leeway’ in determining the reliability of particular expert testimony . . . .”<sup>12</sup>

“[A]n expert’s testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.”<sup>13</sup> An expert’s opinion is reliable if it is “based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation . . . .’”<sup>14</sup> The experts must have good grounds for their opinions, but not necessarily the best grounds or unflawed methods.<sup>15</sup> Courts must consider:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.<sup>16</sup>

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<sup>10</sup> *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008); accord *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741–43 (3d Cir. 1994).

<sup>11</sup> *Whyte v. Stanley Black & Decker, Inc.*, 514 F. Supp. 3d 684, 691 (W.D. Pa. 2021) (citing *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000)).

<sup>12</sup> *Walker v. Gordon*, 46 F. App’x 691, 694 (3d Cir. 2002) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152–53 (1999)).

<sup>13</sup> *Paoli*, 35 F.3d at 742 (citing *Daubert*, 509 U.S. at 587).

<sup>14</sup> *Id.* (quoting *Daubert*, 509 U.S. at 590).

<sup>15</sup> See *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 784 (3d Cir. 1996); *Paoli*, 35 F.3d at 744–45.

<sup>16</sup> *Pineda*, 520 F.3d at 247–48 (citing *Paoli*, 35 F.3d at 742 n.8).

A court must also determine whether the expert’s testimony will assist the trier of fact—*i.e.*, it must evaluate “the ‘fit’ of the expert’s testimony as it relates to the case at hand . . . .”<sup>17</sup>

The fit requirement “goes primarily to relevance.”<sup>18</sup>

### III. DISCUSSION

#### A. Dr. James T. McClave

EPPs have offered the opinions of Dr. James T. McClave on class-wide impact and the calculation of damages in their clobetasol and clomipramine cases. Dr. McClave holds a Ph.D. in statistics from the University of Florida and, before founding his own consulting firm, taught university-level courses in the fields of statistics and economics.<sup>19</sup> Defendants do not challenge Dr. McClave’s qualifications.

In his report, Dr. McClave presents a multiple regression analysis finding impact and damages to end-payers as a result of Defendants’ alleged scheme. Dr. McClave explains that the model specified in his analysis is typical of models that are widely used to estimate overcharges in antitrust cases.<sup>20</sup> According to Dr. McClave, he has employed econometrics analysis in one hundred separate matters.<sup>21</sup> In summary, Dr. McClave’s analysis in this matter is as follows:

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<sup>17</sup> *Macaluso v. Apple, Inc.*, No. 21-1361, 2023 WL 4685965, at \*4 (E.D. Pa. July 21, 2023).

<sup>18</sup> *Daubert*, 509 U.S. at 591.

<sup>19</sup> McClave Corrected Expert Report [Clomipramine], Bank Decl. Ex. 1 at 1-2, No. 16-CM-27242 [Doc. No. 201-3] (hereinafter “McClave Clomipramine Rep.”); McClave Corrected Expert Report [Clobetasol], Bank Decl. Ex. 2 at 1-2, No. 16-CB-27242 [Doc. No. 256-3] (hereinafter “McClave Clobetasol Rep.”). Throughout the discussion, after first reference, where the discussion encompasses both clomipramine and clobetasol documents, the Court cites the relevant clomipramine document.

<sup>20</sup> See McClave Clomipramine Rep. at 23 n.43 (“‘antitrust violation’ listed among types of cases for which ‘regression analysis has been used most frequently.’”) (citing Daniel L. Rubinfeld, *Reference Guide on Multiple Regression*, in *Reference Manual on Scientific Evidence* 303, 306 (3d ed. 2011)).

<sup>21</sup> Tr. of Daubert Hr’g (Sept. 24, 2024) at 38 [MDL Doc. No. 3110].

First, Dr. McClave performed analyses that utilized aggregated, averaged data:<sup>22</sup>

- In Step 1, Dr. McClave tested, at a high level, whether manufacturer list prices such as the Wholesale Acquisition Price (“WAC”) exhibit a correlative relationship with other prices in the clobetasol and clomipramine supply chains.
- In Step 2, Dr. McClave analyzed whether there was any correlation between pharmacy reimbursements and end-payer costs.

After determining that broad trends indicate a high correlative between list prices and actual prices paid by end payers, Dr. McClave performed individualized analyses to assess actual impact and damages:

- In Step 3, Dr. McClave assessed pharmacy acquisition costs encompassed in Defendants’ data to compare prices that pharmacies paid during his “Benchmark Period”<sup>23</sup> to the prices that the pharmacy paid for the product from each defendant during his “Class Period.” Dr. McClave found that more than 99 percent of pharmacies experienced a price increase for each product.<sup>24</sup>
- In Step 4, Dr. McClave used the same data to analyze price increases for end-payers using PBM data, finding that 99 percent of end-payers experienced a price increase for both drugs during the Class Period.<sup>25</sup>

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<sup>22</sup> McClave Clomipramine Rep. § 3.2.

<sup>23</sup> For Clomipramine, the Benchmark Period is January 1, 2009 through February 28, 2013. *See* McClave Clomipramine Rep. at 20. For Clobetasol, the Benchmark Period is January 1, 2009 through May 31, 2014. *See* McClave Clobetasol Rep. at 29.

<sup>24</sup> McClave Clomipramine Rep. § 3.3

<sup>25</sup> *Id.*



- In Step 5, to calculate damages, Dr. McClave conducted Stage 1 of his multiple regression analysis, which controlled—at a transactional level—for innocent market forces to estimate “but for” prices for each pharmacy. Here, Dr. McClave found that more than 99 percent of pharmacies paid elevated prices for both drugs during the Class Period.<sup>26</sup>
- In Step 6, Dr. McClave conducted Stage 2 of his multiple regression analysis and utilized PBM data during the Benchmark period to account for innocent market features in order to determine competitive end-payer drug costs at a transactional level. Here, Dr. McClave compared end-payer drug costs to the output of Stage 1 of his multiple regression analysis to estimate a “passthrough” ratio that Dr. McClave then uses to estimate a “but for” price for each end payer, for each product, in each month of the Class Period.<sup>27</sup>

Defendants ask the Court to exclude Dr. McClave’s report and testimony in the clomipramine and clobetasol cases on the basis of reliability and fit.<sup>28</sup> Defendants advance three primary arguments to exclude Dr. McClave’s testimony. First, Defendants argue that Dr. McClave improperly relies on averaging to show class-wide impact when he should have employed individualized data. Second, they contend that Dr. McClave’s analysis inflates damages because it failed to account for “spread pricing,” Medicare Part D subsidies, and indirect overcharges. Third, Defendants say that Dr. McClave’s analysis does not fit the EPPs’ theory of harm because Dr. McClave does not analyze whether increases in WAC were the product of collusion. Each argument is addressed below.

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<sup>26</sup> McClave Clomipramine Rep. § 4.3.1.

<sup>27</sup> McClave Clomipramine Rep. § 4.4.

<sup>28</sup> Defs.’ Mem. Supp. Mot. Exclude McClave at 8, No. 16-CM-27242 [Doc. No. 201]; Defs.’ Mem. Supp. Mot. Exclude McClave at 8, No. 16-CB-27242 [Doc. No. 256].

### 1. Use of Averaging

First, Defendants argue that Dr. McClave’s analyses present issues of reliability and fit because he took individualized data and “averaged them across all entities,” which they contend is inappropriate in the generic pharmaceutical industry, which they characterize as highly dependent on individual negotiations. According to Defendants, Dr. McClave’s analyses are “based on averaging, [and] contained no testing to exclude the real possibility of individualized differences . . . .”<sup>29</sup> They argue that because end-payers are indirect purchasers, Dr. McClave’s model must demonstrate not only that direct purchasers were overcharged for drugs, but that all direct purchasers individually passed those overcharges on to EPPs.<sup>30</sup> Instead, Defendants say that Dr. McClave’s analysis is unreliable because he utilizes aggregation in a manner that masks the reality that some end-payers suffered no any injury at all.<sup>31</sup> Further, they argue that his use of averaging is unfit to establish antitrust impact because there is no scientific evidence to connect his averages evidence and the inquiry into whether the differential was the result of anticompetitive behavior.

EPPs counter that some of Dr. McClave’s analyses rely on aggregated data to provide “big picture” views of price movement that support inferences that Defendants’ conduct was widespread and that price increases are passed down through the chain of distribution to end-payers. They explain, however, that these illustrations are not Dr. McClave’s models. EPPs put forth that Dr. McClave’s regression analysis examines transactional-level data for all purchases

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<sup>29</sup> Defs.’ Mem. Supp. Mot. Exclude McClave at 12 [Doc. No. 201]. Defendants cite to specific examples where they find issue with Dr. McClave’s analysis: his graphs that demonstrate the close movement of WAC, PAC, and EPP Drug Costs; correlation coefficients that establish correlation between WAC and PAC; aggregated total monthly dollars by all pharmacies; actual PAC and actual EPP costs compared to “one” but-for cost; the assumption that the ratio of EPP costs to PAC would remain constant; and actual costs average. *Id.* at 9-11.

<sup>30</sup> *Id.* at 1.

<sup>31</sup> To demonstrate that at least one pharmacy did not suffer damages, Defendants point to a contract between CVS and Mylan for which they say Mylan did not raise prices even after Mylan raised its WAC on May 16, 2013. *Id.* at 9.

of the bellwether drugs during the class period, creating millions of “but for” prices for each pharmacy and each end-payer. These analyses, they say, are unlike the analyses criticized in cases reflecting aggregate prices applied to all class members. EPPs further argue that this methodology has been accepted by numerous courts, including in the Third Circuit.<sup>32</sup>

In *In re Lamictal Direct Purchaser Antitrust Litig.*, the Third Circuit held that a court considering class certification must perform a rigorous analysis of an expert’s use of averaging to determine whether their use of such averaging is acceptable to certify a class.<sup>33</sup> The use of averaging in data may be most delicate in an industry characterized by many individualized negotiations.<sup>34</sup> Average prices in an expert’s methodology to show impact are problematic because averages “glide[] over” important differences in data.<sup>35</sup>

Defendants urge that in the present matter, Dr. McClave’s methodology runs contrary to Third Circuit law because it masks individual harm through the pervasive use of averages. The Court disagrees. Defendants mischaracterize Dr. McClave’s methodology—in this matter, Dr. McClave has provided a detailed analysis that computes injury at a more granular level than Defendants represent.

In their motion to exclude Dr. McClave, Defendants point to a number of examples that they say exemplify his improper use of averaging: graphs demonstrating trends in list pricing compared to end-payer drug costs, “correlation coefficients” describing correlations between those costs, figures demonstrating aggregate increases in WAC, figures broadly demonstrating

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<sup>32</sup> EPPs.’ Resp. Opp’n Mot. Exclude McClave at 7-11, No. 16-CM-27242 [Doc. No. 222]; EPPs.’ Resp. Opp’n Mot. Exclude McClave at 7-11, No. 16-CB-27242 [Doc. No. 297].

<sup>33</sup> See 957 F.3d 184, 194 (3d Cir. 2020).

<sup>34</sup> *Id.* (noting that the acceptability of averages in an expert report depends on the answer to multiple factual predicates).

<sup>35</sup> See *Sheet Metal Workers Loc. 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, No. CIV.A. 04-5898, 2010 WL 3855552, at \*30 (E.D. Pa. Sept. 30, 2020).

the relationship between end-payer costs and Pharmacy Acquisition Costs, variation in EPP cost ratios and Pharmacy Acquisition Costs to EPP costs, and in his damages calculation through averaging of actual costs less average amounts paid across all pharmacies.

Dr. McClave does perform several analyses in his report that rely on aggregated or averaged data. In his deposition and testimony, however, Dr. McClave makes clear that his use of these figures is meant to be illustrative and that, with regard to impact, the crux of his work was performed on a transaction-by-transaction basis to calculate impact for each individual entity.<sup>36</sup> In section 3.2 of his report, he begins his review of the bellwether drugs by producing a chart of averaged figures to illustrate broad pricing trends. These figures, however, are an introduction to—rather than the core of—Dr. McClave’s work. And although Dr. McClave uses weighted averages in his charts to identify broad trends in data to demonstrate central tendency, he separately performs analyses that calculate impact at a transactional level. To the extent that Defendants disagree with his analysis and his determination of impact, their arguments go to the weight of his testimony, not its admissibility.

Regarding his use of a weighted average of actual pharmacy acquisition costs, Defendants contend that Dr. McClave “[relied] on average pharmacy acquisition costs” and that his use of those average costs “masks uninjured class members and impacted transactions.”<sup>37</sup> Again, however, Dr. McClave’s analysis examines injury on a transaction-by-transaction basis to support his findings. Dr. McClave’s report considers substantial variations in prices paid by

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<sup>36</sup> “Because this was just the first step. This was a high-level picture. I intended from the very beginning and did, with the last two-thirds of my report, to get into individual price analysis.” Tr. of Daubert Hr’g (Sept. 24, 2024) at 50 [MDL Doc. No. 3110]. *See also* McClave Dep. Tr., Bank Decl., Ex. 3, at 342, No. 16-CM-27242–43 [Doc. No. 201-5] (hereinafter “McClave Dep.”); Bank Decl. Ex. 3 at 342-43 [Doc. No. 256-4].

<sup>37</sup> Tr. of Daubert Hr’g (Sept. 24, 2024) at 28 [MDL Doc. No. 3110].

individual class members based on factors such as the form of the drug.<sup>38</sup> Dr. McClave’s damages model adjusted his average pharmacy acquisition cost according to hundreds of thousands of estimated cost ratios accounting for the type of end payer, business, and product level.<sup>39</sup> Here again, Defendants’ criticisms of his use of averaging of pharmacy acquisition cost to demonstrate overcharges may test the weight of his opinions, but do not render them unreliable.

The Court determines that Dr. McClave’s use of averaging was appropriate under *Daubert* standards because he conducted individual analyses to find impact and, where he used averaging to calculate damages, those averages do not render his methodology unreliable.

## 2. Inflated Damages

Defendants next argue that Dr. McClave’s analysis ignores the complexity of the generic drug market, does not account for pass-through, and fails to establish a link between Defendants’ alleged conduct and overcharges. Defendants argue that Dr. McClave attributes factors outside of their control to overcharges, namely: (1) spread pricing by PBMs, (2) Medicare Part D subsidies, and (3) that Dr. McClave improperly attributed overcharges to Defendants because it does not disentangle overcharges paid by uninjured pharmacies.<sup>40</sup>

In an antitrust case, an expert’s damages model “need not be exact.”<sup>41</sup> Plaintiffs are required to present a “reasonable estimate” of damages.<sup>42</sup> “Any other rule would enable the

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<sup>38</sup> See, e.g., *Lamictal*, 957 F.3d at 194 (listing factors appropriate to resolving factual disputes regarding averages).

<sup>39</sup> Tr. of Daubert Hr’g (Sept. 24, 2024) at 92-93 [MDL Doc. No. 3110].

<sup>40</sup> Defs.’ Mem. Supp. Mot. Exclude McClave at 13-19 [Doc. No. 201].

<sup>41</sup> *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013).

<sup>42</sup> *Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 484 (3d. Cir.1998).

wrongdoer to profit by his wrongdoing at the expense of his victim.”<sup>43</sup> Plaintiffs argue that Dr. McClave provided a reasonable estimate of damages, as required by Third Circuit precedent,<sup>44</sup> and that multiple regression models are a well-accepted form of analysis.

The Court agrees that Dr. McClave has provided a reasonable estimate of damages. First, the practice of spread pricing by PBMs occurs when the PBM’s payment to the pharmacy and the client’s payment to the PBM differ,<sup>45</sup> creating a portion of monetary exchange between a pharmacy and a payer, such as an insurer, that a PBM may retain as profit. EPPs argue that, because spread pricing existed during the Benchmark Period, Dr. McClave’s model already includes the effects of spread pricing in a competitive market and that the prevalence of spread pricing remained flat during the Benchmark and Class Periods. Further, EPPs argue that the PBM market was already concentrated during the Benchmark Period and that there was no material change in PBM concentration between the two periods.<sup>46</sup> The parties debate the extent to which spread pricing may have had an effect on generics pricing during the Class Period. Dr. McClave’s analysis does include a measure of spread pricing between the two periods, both by what is “baked in” to his initial model and in his supplemental regression model that estimates what spread prices would have been absent the conspiracy. Addressing this issue in testimony, Dr. McClave explained that spread pricing is inherent in his analysis:

“Spread pricing occurred in both periods. So by using the benchmark period, I had transactions that included spread in my analysis. And so the but-for prices that I estimated also include allowance for spread. And I think it's important, Your Honor, to

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<sup>43</sup> *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 124 (1969) (quoting *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264–65 (1946)).

<sup>44</sup> *Rossi*, 156 F.3d at 484.

<sup>45</sup> Hughes Expert Report [Clomipramine], Bank Decl. Ex. 6 ¶ 52, No. 16-CM-27242 [Doc. No. 201-8] (hereinafter “Hughes Clomipramine Rep.”); Hughes Expert Report [Clobetasol], EPP’s Mem. Supp. Mot. Exclude Hughes Ex. 2 ¶ 53, No. 16-CB-27242 [Doc. No. 290-2] (hereinafter “Hughes Clobetasol Rep.”).

<sup>46</sup> EPPs’ Resp. Opp’n Mot. Exclude at McClave at 11-21 [Doc. No. 222].

note that about 75 percent of transactions in both periods don't have spread included. It's only about a quarter of the transactions that do.”<sup>47</sup>

Next, Defendants’ expert Dr. Hughes takes issue with Dr. McClave’s model for omitting price offsets resulting from Medicare Part D subsidies. Medicare Part D plans are privately-administered, government-subsidized plans that generally cover outpatient prescription medicines.<sup>48</sup> The federal government pays for “virtually all costs” for prescriptions under these plans through direct subsidies and reinsurance payments, which Dr. Hughes argues means that a Medicare Part D sponsor “may not bear any of the cost of the drugs purchased by its enrollees . . . .”<sup>49</sup> But nothing in the record suggests that not including Medicare Part D subsidies was a grave error on Dr. McClave’s part, and Defendants do not cite caselaw that indicates an expert’s testimony should be excluded if they do not offset damages to account for Part D subsidies. EPPs, however, argue that “numerous” courts have “concluded that Medicare Part D subsidies are irrelevant to damages....”<sup>50</sup> Indeed, one court recently excluded similar analysis from Dr. Hughes that Medicare Part D payments and rebates can diminish antitrust injury.<sup>51</sup> Whether Dr. McClave’s damages analysis should account for subsidies goes to the weight of his opinions, but is not so clearly unreliable that his model should be excluded for lack of attention to the issue. The issue is one that reasonable experts may disagree on and is better suited to be addressed during trial.

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<sup>47</sup> Tr. of Daubert Hr’g (Sept. 24, 2024) at 62-63 [MDL Doc. No. 3110].

<sup>48</sup> Hughes Clomipramine Rep. at ¶ 13.

<sup>49</sup> *Id.*

<sup>50</sup> EPPs’ Resp. Opp’n Mot. Exclude at McClave at 19-20 [Doc. No. 222]. See *In re HIV Antitrust Litig.*, 2023 WL 3603732, at \*2-3 (N.D. Cal. May 23, 2023) (barring Medicare Part D offset arguments at trial); *In re Zetia (Exetimibe) Antitrust Litig.*, 2023 WL 3064462, at \*5 (E.D. Va. Apr. 18, 2023) (excluding evidence of Part D payments because such payments were not “directly traceable to the EPPs’ expenditures” for the relevant drugs).

<sup>51</sup> *Gov’t Emps. Health Ass’n v. Actelion Pharm. Ltd.*, No. CV GLR-18-3560, 2024 WL 4122123, \*14-17 (D. Md. Sept. 6, 2024) (“The Court will exclude only Dr. Hughes’ opinions and testimony that rebates and Medicare Part D payments negate antitrust injury.”).

Finally, Defendants argue that Dr. McClave’s analysis includes indirect overcharges that were not directly caused by *direct* overcharges that were passed through to end-payers. EPPs, however, have not yet had the chance to prove that portion of their argument and intend to “present compelling evidence of both liability and damages that will allow a reasonable jury to conclude that third party payors’ (“TPPs”)’ overpayments for clobetasol and clomipramine were caused by Defendants’ anticompetitive conduct.”<sup>52</sup> Thus, this issue at present is premature and goes to EPPs’ burden of proving liability, not to the soundness of Dr. McClave’s damages model for the purposes of class certification.<sup>53</sup>

### 3. Comcast Issue

Defendants next argue that Dr. McClave’s impact and damage analysis does not fit theories of price-fixing, market allocation, and bid rigging. Defendants present *Comcast Corp. v. Behrend*,<sup>54</sup> in which the Supreme Court held that Dr. McClave’s proposed method of calculating an antitrust violation in that case was flawed because it did not measure damages from any antitrust injury. Defendants suggest that Dr. McClave has committed the same error in this case. Plaintiffs, however, criticize Defendants’ use of *Comcast* in these cases and indicate that the decision has no relevance here. Further, Plaintiffs argue that Dr. McClave’s models do not measure any one type of conduct.

In *Comcast*, Respondents proposed four separate theories of antitrust impact to certify a class of Comcast subscribers under Rule 23(b)(3) for alleged damages of federal antitrust laws.<sup>55</sup> The district court in that matter accepted only one theory as capable of class-wide proof, rejecting

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<sup>52</sup> EPPs.’ Resp. Opp’n Mot. Exclude McClave at 21 [Doc. No. 222].

<sup>53</sup> Dr. McClave has testified that, if it became imperative later in the case to remove potential uninjured transactions, he would be able to do so. *See* Tr. of Daubert Hr’g (Sept. 24, 2024) at 75 [MDL Doc. No. 3110].

<sup>54</sup> 569 U.S. 27 (2013).

<sup>55</sup> *Id.* at 30-31.



the rest in its certification order.<sup>56</sup> To certify class in that case, Respondents' expert Dr. McClave<sup>57</sup> offered a regression model that the Supreme Court later determined did not properly isolate damages resulting from any of the particular theories of impact put forth by the plaintiffs, and thus was not appropriately tied to the remaining theory of impact in the case.<sup>58</sup> Finding issue with Dr. McClave's model, Justice Scalia held that "[i]t follows that a model purporting to serve as evidence of damages in this class action must measure only those damages attributable to that theory," because any model at class certification must be consistent with a plaintiffs' theory of liability.<sup>59</sup> In *Comcast*, Dr. McClave's flaw was that his model assumed the validity of the three theories of impact that had been excluded from the case. Dr. McClave's model could not reliably demonstrate impact to the class from the remaining theory advanced by the class because it could not disaggregate "that single theory's effect from the effects of the three theories not suitable for class treatment."<sup>60</sup> The Court reasoned, however, that his methodology may well been determined to be sound if those theories had remained in the case.<sup>61</sup>

In the present cases, Dr. McClave has not relied on any premise for his conclusions that no longer apply. His data exists to support EPPs' argument, but his analysis is not specific to or exclusive of any particular theory of harm. In *Comcast*, Dr. McClave's regression model was designed to calculate damages from those four theories of impact and was not able to isolate damages attributable to the remaining theory.<sup>62</sup> Similarly, In *In re Processed Egg Prod. Antitrust*

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<sup>56</sup> *Id.*

<sup>57</sup> Dr. McClave, currently offered in this case as EPPs' expert, served as Respondents' expert in *Comcast*.

<sup>58</sup> *Comcast*, 569 U.S. at 32.

<sup>59</sup> *Id.* at 35.

<sup>60</sup> See *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 171, 192. (E.D. Pa. 2015)(explaining the posture of *Comcast*).

<sup>61</sup> *Id.* at 36.

<sup>62</sup> *Comcast*, 569 U.S. at 31.

*Litig.*, Judge Pratter declined to extend *Comcast* to a class action antitrust case at a stage in which all theories of liability remained viable.<sup>63</sup> To do so, she reasoned, would require plaintiffs to separate each anticompetitive action and measure the effects of those isolated actions in turn.<sup>64</sup> Further, Judge Pratter reasoned that to extend *Comcast* so broadly would prematurely and improperly engage with merits at class certification.<sup>65</sup> Here too, EPPs' theory of liability has not been found inappropriate for class treatment. At this stage in litigation, the Court is not required to ensure that EPPs are able to withstand any "possible development" in compliance with Rule 23 moving forward.<sup>66</sup>

Accordingly, Defendants' motion to exclude Dr. McClave's opinions and testimony is denied.

#### **B. Dr. James W. Hughes**

Defendants present Dr. James W. Hughes to opine on class-wide injury and damages and whether individualized inquiry is necessary to assess antitrust injury and damages to the members of the proposed classes. Dr. Hughes is a professor emeritus of economics at Bates College specializing in the fields of Industrial Organization, Law and Economics, Health Economics, Environmental Economics, and Labor Economics. He holds a Ph.D. in Economics

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<sup>63</sup> 312 F.R.D. at 192.

<sup>64</sup> *Id.*

<sup>65</sup> *See id.* ("Although the Court must engage with the merits of the case when they weigh upon the Court's analysis of Rule 23, the Court must not engage in 'free-ranging merits inquiries at the certification stage.'") (citing *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 568 U.S. 455, 465-66).

<sup>66</sup> *Id.* at 193 ("Defendants ask the Court to ensure that compliance with Rule 23 will withstand any possible development moving forward. That is not what *Comcast* required, as implied by the Supreme Court's note that the plaintiffs' methodology in *Comcast* 'might have been sound . . . if all four of those alleged distortions remained in the case.'") (quoting *Comcast*, 569 U.S. at 37).

from the University of Michigan.<sup>67</sup> EPPs do not challenge his qualifications, except on the limited point of expertise in health insurance premiums.<sup>68</sup>

Reviewing EPPs' experts' reports, Dr. Hughes reaches two primary conclusions. First, Dr. Hughes finds that EPPs' experts should have assessed individualized injury in the proposed classes. Second, that EPPs' expert damages calculations were unreliable and overstated. EPPs seek to exclude a subset of Dr. Hughes's opinions as unreliable and unfit for the facts of these cases: (1) Dr. Hughes's opinions on whether EPPs can demonstrate antitrust injury through common proof, specifically, whether insurers are injured when they pass on overcharges to customers in the form of higher premiums, and whether EPPs can establish class-wide injury; (2) Dr. Hughes's opinion that EPPs who purchased clomipramine from CVS during the class period were not injured; and (3) Dr. Hughes's criticisms of Dr. McClave's regression model.

### *1. Injury and Causation*

#### *Injury*

EPPs assert that Dr. Hughes utilizes an incorrect measure of antitrust injury that does not fit the facts of these cases and would likely mislead the fact finder. Specifically, EPPs take issue with Dr. Hughes's definition of antitrust injury as well as his opinions that injury is offset when an otherwise injured end-payer passes overcharges on through increased insurance premiums.

Defendants retained Dr. Hughes in part to assess whether there is common evidence to establish class-wide antitrust injury.<sup>69</sup> Based on his review of the findings of EPPs' experts, Dr. Hughes determined that reports by those experts had not constructed a feasible and reliable

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<sup>67</sup> Hughes Clomipramine Report at ¶¶ 1-3.

<sup>68</sup> Tr. of Daubert Hr'g (Sept. 24, 2024) at 154 [MDL Doc. No. 3110].

<sup>69</sup> Hughes Clomipramine Rep. at ¶ 11.

methodology for determining class-wide injury. But Dr. Hughes criticisms on injury are invalid, EPPs argue, because he assesses whether potential class members paid lower prices **overall** in the actual world or “but-for” world. EPPs argue that his understanding of injury conflicts with well-settled law, which holds even one transaction at a supercompetitive price constitutes an injury—even if other transactions occurred below the competitive level. Dr. Hughes clarified in his testimony in this matter that his definition of injury is not *legal*, but rather corresponds to an economist’s understanding of injury. Dr. Hughes confirms that his analysis of injury, as an economist, evaluates whether parties have been made better or worse overall following an alleged conspiracy:

Q And so the record's clear. Did you use a legal definition of antitrust injury in your reports?

A No, I did not.

Q And why not?

A Well, testifying as an economist, I'm here as an economist. And so I generally use, as an economist, how economists view injury, and that **simply is the entity better off or worse off in the but-for world compared to the actual world.**<sup>70</sup>

Further, Dr. Hughes’s report on the bellwether drugs specifies that “[a]ny assessment of injury needs to account for the degree of pass-through from the manufacturer sector to members of the proposed classes.”<sup>71</sup> According to Dr. Hughes’s report, where a health plan has been able to “completely pass on” an increased cost to beneficiaries, “those insurers and health plans are

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<sup>70</sup> See also Hughes Dep. Tr., EPP’s Mem. Supp. Mot. Exclude Hughes Ex. 3 at 82-87, No. 16-CM-27242 [Doc. No. 229-3]; Hughes Dep. Tr., EPP’s Mem. Supp. Mot. Exclude Hughes Ex. 3 at 82-87, No. 16-CB-27242 [Doc. no. 290-3] (hereinafter “Hughes Dep.”) (“If there are -- to an economist, if there are enough transactions that are below the so-called competitive level such that the third-party payer's total expenditure on that product is the same in the actual and but-for world, then to an economist I believe a third-party payer would not be injured”) (emphasis added).

<sup>71</sup> See e.g., Hughes Clomipramine Rep. at ¶101.

not injured by the alleged conduct.”<sup>72</sup> Further, Dr. Hughes testified to the “basic” principle that EPPs are not injured to the extent that they did not fully bear the brunt of an overcharge:

It's basic economics that -- and it's agreed to. It's in the plaintiffs' filings, in the plaintiffs' reports. Economic principles say that when costs go up, prices have to go up. And that's the basis of their assumption that there's 100 percent pass-on at every stage of the process.

But when that alleged overcharge reaches EPPs, then plaintiffs' experts say, oh, it stops, and EPPs bear the entire cost of the alleged overcharge. And my opinion is that basic economics goes farther than that. The insurance companies or the health plans are businesses themselves, and it's incumbent upon them to ultimately pass on higher costs or they're going to go out of business or suffer a reduction in profits.

And so in order to determine whether or not EPPs actually were injured, and if they were injured to what extent they bore any overcharge, you have to take into account the degree to which and whether they passed on that overcharge in the form of a higher premium to their rate payers.<sup>73</sup>

Antitrust injury occurs when a purchaser incurs a single overcharge.<sup>74</sup> The Court's assessment of injury will not contemplate whether the entity incurring the overcharge was later able to offset its financial burden by raising prices.<sup>75</sup> Whether or not an entity bears the ultimate cost of an overcharge, courts are clear that injury and damages are distinct and that “if a class member is overcharged, there is an injury....”<sup>76</sup> Pass-through and offset are thus more appropriately applied to adjust a plaintiff's measure of damages—not to assess whether an injury

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<sup>72</sup> Hughes Clobetasol Rep. at ¶ 170.

<sup>73</sup> Tr. of Daubert Hr'g (Sept. 24, 2024) at 174–75 [MDL Doc. No. 3110].

<sup>74</sup> See *In re Niaspan Antitrust Litigation*, 464 F.Supp. 3d 678, 709 (E.D. Pa 2020) (“In contemplation of law the claim for damages arose at the time the extra charge was paid.”) (quoting *Adams v. Mills*, 286 U.S. 397, 407 (1932)). The Supreme Court has held that “courts will not go beyond the fact of this injury to determine whether the victim of the overcharge has partially recouped . . .” *Hawaii v. Standard Oil of Cal.*, 405 U.S. 251, 262 n.14 (1972). See also *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015) (“antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset.”).

<sup>75</sup> See *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 487-94 (1968).

<sup>76</sup> *In re Nexium Antitrust Litig.*, 777 F.3d at 27.

occurred. In addition, an expert's testimony must be helpful to the fact finder, and thus cannot espouse opinions that are contrary to law.<sup>77</sup>

Defendants argue that EPPs' arguments regarding Dr. Hughes's definition of antitrust injury fall short because Dr. Hughes was not asked to opine on the legal definition of injury. Defendants mischaracterize EPPs' critiques on the matter. Regardless of whether Dr. Hughes offered a definition of injury in his report or was asked to do so, his understanding of injury must nonetheless be consistent with the legal definition. Dr. Hughes opines that the "overall situation" is crucial to determining whether injury has occurred and that an end-payer who paid one overcharge is not injured if enough of that payer's transactions occurred at a supracompetitive level.<sup>78</sup> The understanding of antitrust injury that Dr. Hughes espouses in his testimony and deposition is directly at odds with Third Circuit law and is thus unfit for the present matter. Courts do not consider whether antitrust injury occurs on an overall basis—a court's inquiry on the matter is limited to determining whether a single overcharge occurred. How many overcharges occurred and whether an entity was better off in a post-conspiracy or but-for world is a question for damages calculations.

Thus, Dr. Hughes's testimony that economic injury occurs only when the overall situation is worse for a plaintiff is likely to mislead a jury. Further, it is not clear that even where

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<sup>77</sup> Fed. R. Ev. 702(a) requires that an expert's testimony "help the trier of fact." See *Gov't Emps. Health Ass'n*, 2024 WL 4122123, \*6-7 (D. Md. Sept. 6, 2024) (collecting cases).

<sup>78</sup> Hughes Dep. at 86:14-87:15 ("If there are -- to an economist, if there are enough transactions that are below the so-called competitive level such that the third-party payer's total expenditure on that product is the same in the actual and but-for world, then to an economist I believe a third-party payer would not be injured.").

he examined injury on a more granular basis that his analysis is based on the presumption that one overcharge leads to antitrust injury.<sup>79</sup>

Dr. Hughes’s assessment of pass-through using insurance premiums similarly conflicts with established law. The District Court of Maryland in *Government Employees Health Association v. Actelion Pharm. LTD.*, recently reevaluated Dr. Hughes’s assessment of antitrust injury and his opinions that Medicare Part D payments and rebates offset injury in an antitrust matter.<sup>80</sup> That court excluded Dr. Hughes’s opinions on the basis that they conflicted with established law. In *Government Employees*, the court opined that Dr. Hughes’s argument that rebates can negate antitrust injury had previously been rejected by several courts, and that the Defendant “conflates injury with damages” where it “argues that some TPPs who allegedly overpaid . . . were not injured because they were later reimbursed for those overcharges.”<sup>81</sup> In the matter before this Court as well, Dr. Hughes’s opinion conflates injury with damages. Although Dr. Hughes is free to opine that EPPs’ experts should offset their *damages* where pass-through occurs, testimony that the degree to which payers increase prices to recoup losses affects whether they have suffered an *injury* is unfit testimony in these cases. As in the case before the District Court of Maryland, Dr. Hughes’s opinions are contrary to established law.

EPPs also contend that Dr. Hughes’s opinions that entities that purchased clomipramine from CVS Pharmacy were not injured during the class period must be excluded. They contend that his opinions are unreliable because he does not use the correct definition of injury, because

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<sup>79</sup> Defendants also claim that Dr. Hughes did look at individual transactions and point to several examples listed during his deposition. Even in those examples, Dr. Hughes opines that injury for an entity is indeterminable where “only a few claims associated with Defendants’ products incurred higher drug prices.” *See e.g.*, Hughes Clobetasol Report at ¶ 154.

<sup>80</sup> 2024 WL 4122123 (D. Md. Sept. 6, 2024).

<sup>81</sup> *Id.* at \*6.

his opinions are methodologically flawed and ignore the critical information that CVS did not purchase clomipramine solely from Mylan during the Class Period, and because Dr. Hughes did not conduct empirical analysis to assess whether Defendants' conduct impacted TPP prices for clomipramine at Mylan.

Dr. Hughes's definition of antitrust injury in tandem with his opinions regarding the necessity of assessing pass through to evaluate injury render his opinions on injury unreliable and potentially misleading to the trier of fact. Those opinions represent an incorrect understanding of the underlying standard applicable in these cases. If Dr. Hughes's opinion is that EPPs' experts' reports are flawed because they cannot remove allegedly uninjured plaintiffs, his own analysis must be able to reliably identify whether a class member has suffered injury. He cannot do so because his views on injury are fundamentally flawed. Similarly, Dr. Hughes cannot opine on whether purchasers from CVS were injured because his evaluation of injury is flawed.

Dr. Hughes's opinions on whether EPPs can demonstrate class-wide injury, including his opinions regarding injury flowing from purchases from CVS and whether injury is diminished because those payers passed on overcharges to customers, are excluded.

#### *Qualifications on Insurance Premiums*

In addition to their challenge to the reliability of Dr. Hughes's opinions concerning insurance premiums, EPPs put forth a challenge to Dr. Hughes's qualifications to opine on the setting of health insurance premiums. Dr. Hughes has not researched or published articles concerning the issue of insurance premium setting. He does offer, however, that he served as the chair of the benefits committee at Bates College and, in that capacity, reviewed insurance



proposals by a number of companies.<sup>82</sup> EPPs contest that his work at Bates College is not sufficient for Dr. Hughes to form opinions on the inner workings of insurance companies or the intricacies of premium rate setting.<sup>83</sup>

To be qualified to offer an opinion, an expert must have specialized training or experience in a particular field.<sup>84</sup> Dr. Hughes is clearly a well-qualified health economist and EPPs do not challenge his qualifications as they pertain to evaluating the economics of health and antitrust. The Court agrees, however, that he is not qualified to opine on health insurance premium rate setting. Dr. Hughes has not published an article on rate setting, nor does he offer any specialized training or insight into the field except his experience as the chair of the benefits committee at Bate College. Despite his deep knowledge of health economics, his work negotiating with health insurance companies in that capacity did not necessarily make him privy to the inner workings of those companies or provide a basis of expertise that goes beyond what the average layperson knows on the matter.

To the extent that Dr. Hughes intends to testify on health insurance premium rate setting, his opinions are excluded because he is not qualified to do so.

### *Correlation*

Among his criticisms of Dr. McClave's report, Dr. Hughes opines that Dr. McClave's models on correlatives between list prices and end-payer costs are deficient because "[i]t is critical to note that the size and statistical significance of correlation coefficients say *nothing*

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<sup>82</sup> Tr. of Daubert Hr'g (Sept. 24, 2024) at 184-85 [MDL Doc. No. 3110].

<sup>83</sup> EPPs.' Mem. Supp. Mot. Partially Exclude Hughes at 12-13, No. 16-CM-27242 [Doc. No. 229]; EPP's Mem. Supp. Mot. Partially Exclude Hughes at 12-13, No. 16-CB-27242 [Doc. No. 290]. Epps argue further that Dr. Hughes's opinions on insurance premiums are flawed because premium rates are set on an aggregate basis and cannot typically be traced to overcharges for a specific drug. *Id.*

<sup>84</sup> See *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003).

about *causation*. No correlation coefficient can be interpreted by itself as indicating that movements in one data series cause the movement in the other data series.”<sup>85</sup> EPPs disagree with Dr. Hughes’s characterization of the relationship between correlation and causation and argue that his description is extreme and unsound.

Dr. Hughes’s opinions that correlation says nothing about causation are potentially misleading and thus unfit. Correlation coefficients are a widely accepted method of testing the strength between two variables.<sup>86</sup> Although Defendants cite to cases that have held that a party cannot draw causation from correlation alone, Dr. McClave performed a slightly different analysis here. Dr. McClave elaborated on correlation coefficients and, in his reply report, explains that a causal relationship can be inferred where the change in the causal variable precedes the change in the outcome variable and there exists a strong correlation between the two.<sup>87</sup>

This may well be the difference between two expert opinions, which typically would be left to the trier of fact to resolve.<sup>88</sup> But in this matter, the Court finds Dr. Hughes’s opinion—that correlation can say *nothing* about causation—problematic and potentially misleading to the trier of fact. While Dr. Hughes may critique Dr. McClave’s correlative analyses, it is outside the norm to opine that correlation is completely unrelated to causation. Further, it does not fit the analysis

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<sup>85</sup> Hughes Clomipramine Rep. ¶ 108 (emphasis in original).

<sup>86</sup> See e.g., 1 *Mod. Sci. Evidence* § 5:43 *Correlation and regression—Generally* (2023-2024 Edition) (“Regression models are often used to infer causation from association; for example, such models are frequently introduced to prove disparate treatment in discrimination cases, or to estimate damages in antitrust actions.”).

<sup>87</sup> McClave Reply Expert Report [Clomipramine], EPPs’ Mem. Opp’n Mot. Exclude McClave Ex. No. 3 at § 3.2, No. 16-CM-27242 [Doc. No. 222-4] (hereinafter “McClave Clomipramine Reply Rep.”); McClave Reply Expert Report [Clobetasol], EPP’s Mem. Opp’n Mot. Exclude McClave Ex. No. 2 at § 3.2, No. 16-CB-27242 [Doc. No. 284-2, 284-3] (hereinafter “McClave Clobetasol Reply Rep.”).

<sup>88</sup> See *In re Asbestos Products Liability Litigation (No VI)*, 714 F. Supp. 2d 535, 547 (observing that “[t]he ultimate determination of whether expert testimony is correct and ‘reliable’ in this sense remains with the jury.”).

in this case, where Dr. McClave has opined on factors that strengthen the correlative inference between two variables with a strong market relationship. To that end, Dr. Hughes overstates his critique in a manner that could be misleading to the fact finder regarding the appropriate weight to give correlation analyses.

Dr. Hughes's opinions on correlation are excluded to the extent that he testifies or opines in his report that *no* inferences can be drawn from correlation coefficients.

## 2. Criticisms of Dr. McClave's Regression Analysis

EPPs challenge Dr. Hughes's criticism of Dr. McClave's regression model as unreliable, arguing that Dr. Hughes relies on an incorrect understanding of antitrust injury, that he has a subjective view of regression analyses in these cases, and that his views are not based on empirical testing. In fact, EPPs note that Dr. Hughes has never opined that a multiple regression analysis can reliably demonstrate impact in class action price fixing cases.<sup>89</sup> In response, Defendants argue that EPPs must bear the burden of offering a valid methodology for establishing injury and damages, and that it is not material whether Dr. Hughes offers a methodology of his own.

Defendants cite several cases in which the Second Circuit has held that the duty of a rebuttal expert is different from an affirmative expert.<sup>90</sup> The Court agrees that a rebuttal expert

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<sup>89</sup> EPPs.' Mem. Supp. Mot. Exclude Hughes at 16 [Doc. No. 229].

<sup>90</sup> See e.g., *Capri Sun GmbH v. Am. Beverage Corp.*, 595 F.Supp. 3d 83, 140 (S.D.N.Y. 2022) ("At bottom, a rebuttal expert need not proffer a methodology or model, but only critique the opposing expert's."); *In re Payment Card Interchange Fee and Merchant Discount Antitrust Litig.*, 638 F.Supp.3d 227, 268 (E.D.N.Y. 2022) (expressing that an expert does not need to offer a "competing analysis" but may criticize opinions by another party); *Luitpold Pharms., Inc. v. Ed. Geistlich Sohne A.G. Fur Chemische Industrie*, 2015 WL 5459662, at \*12 (S.D.N.Y. Sept. 16, 2015) ("A rebuttal expert, by nature, criticizes the methodology and/or opinions of another. There is no requirement that a rebuttal expert himself offer a competing analysis; his opinions may properly concern criticizing that presented by another party"); *In re Zyprexa Prods. Liab. Litig.*, 489 F.Supp. 2d 230, 285 (E.D.N.Y. 2007) ("[D]efendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts.").

need not necessarily produce a competing analysis to the methodology that they criticize. But because all experts must meet the *Daubert* standards, if a rebuttal expert is to discredit another expert's model by making affirmative statements or findings of their own they must still provide good grounds based in methods and principles of analytical evaluation to ground their opinions that discredit an analytical expert opinion.

EPPs ask the Court to exclude Dr. Hughes's opinions on Dr. McClave's regression.<sup>91</sup> The fact that Dr. Hughes has never opined that a regression analysis is capable of showing class-wide injury, which EPPs point out is a widely accepted method used in price-fixing cases, is concerning. But this fact does not necessarily render his opinions unreliable if they are nonetheless based on good grounds, although it may bear on the weight of his testimony and provide fodder for cross-examination. And, as previously discussed, to the extent that Dr. Hughes's criticisms of Dr. McClave's model touch on Dr. McClave's analysis of injury, they are excluded.

More concerning is EPPs' assertion that Dr. Hughes has not used any methodology involving empirical testing in his critiques—not just that he has not offered any competing model. The Court agrees that Dr. Hughes need not have provided a competing model recreating Dr. McClave's entire methodology or offering an alternative model to calculate impact, which is EPPs' burden. But where Dr. Hughes does functionally suggest alternative methods for assessing impact to pharmacies without conducting his own sound assessment to test his opinions, his critique falls short of being reliable. In his own analysis of Dr. McClave's findings, Dr. Hughes

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<sup>91</sup> EPPs.' Mem. Supp. Exclude Hughes at 16-18 [Doc. No. 299].

did not conduct any empirical analysis to demonstrate the supposed flaws in Dr. McClave's models, despite the fact that he has done so in previous cases.<sup>92</sup>

Dr. Hughes's critiques go beyond merely stating that Dr. McClave failed to consider certain factors. In Dr. Hughes's assessment of Dr. McClave's benchmark period, Dr. Hughes specifies that he "do[es] not attempt to re-estimate Dr. McClave's regression specifications or propose an alternative benchmark period methodology, but rather to illustrate the significance of selecting a proper benchmark."<sup>93</sup> Yet in the very same paragraph that Dr. Hughes states he does not attempt to propose an alternative benchmark period, he does just that. Dr. Hughes suggests that Dr. McClave should have considered the period after the proposed class period instead of the period before, which Dr. McClave employs in his model.<sup>94</sup> Dr. Hughes provides estimates employing his proposed benchmark period but does not conduct his own analysis to verify the validity of his alternative. Without that analysis, Dr. Hughes's critique is unreliable, and he does not form good grounds on which to present his findings. Dr. Hughes cannot escape the necessity of providing rigorous scientific analysis of his opinions simply by stating that he does not intend to put forth an alternative benchmark period when he, in fact, proposes an alternative benchmark period.

EPPs' motion to partially exclude Dr. Hughes's opinions is granted.

### **C. Dr. Erin E. Trish**

Defendants offer Dr. Erin E. Trish as an expert to explain the drug supply chain, to analyze the role of intermediaries—including pharmacies and PBMs—in generic pricing, and to

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<sup>92</sup> See *Lamictal* 957 F.3d at 193-94 (detailing Dr. Hughes' rebuttal expert report in previous case).

<sup>93</sup> Hughes Clomipramine Rep. at ¶ 178.

<sup>94</sup> *Id.* (estimating the effect on Dr. McClave's damages estimates if Dr. McClave had used 2019 onwards [after the close of the proposed class period] as a benchmark period).

review opinions by Plaintiffs' experts on those topics. She is the co-director of the USC Schaeffer Center for Health Policy and Economics. She holds a Ph.D. in Health Policy and Economics from Johns Hopkins University's Bloomberg School of Public Health.<sup>95</sup> EPPs do not challenge Dr. Trish's credentials.

Dr. Trish presents three primary critiques of Plaintiffs' experts' analyses related to the impact of PBMs' business practices on end payer costs for clobetasol and clomipramine: (1) that their claims of a link between manufacturer list prices and end payer costs are inconsistent with their own analysis of "highly aggregated data" as well as with more disaggregated data; (2) that Dr. McClave's model does not account for the impact of spread pricing, and (3) that Dr. McClave's model does not account for PBM reconciliation payments to end payers after the point of sale.<sup>96</sup>

EPPs move to exclude Dr. Trish's report and testimony in substantial part, as her opinions relate to brand rebates, post-conspiracy materials, other pricing tools, spread pricing, and impact and pass-through of injury.<sup>97</sup> EPPs advance two primary arguments to exclude Dr. Trish's opinions: First, EPPs argue that Dr. Trish relies on irrelevant and unreliable material, including brand rebates, post-class materials, pending investigations, unenacted legislation, and "other pricing tools" employed by PBMs to increase prices paid by TPPs. Second, EPPs argue that Dr. Trish's opinions on spread pricing are methodologically unsound because she does not

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<sup>95</sup> Bank Decl., Ex. 8, Trish Expert Report [Clomipramine], at ¶¶ 1-4 [Doc. No. 201-10] (hereinafter "Trish Clomipramine Rep."); Bank Decl., Ex. 12, Trish Expert Report [Clobetasol], at ¶¶ 1-4 [Doc. No. 201-14] (hereinafter "Trish Clobetasol Rep.).

<sup>96</sup> Trish Clomipramine Rep. at 7-11.

<sup>97</sup> A breakdown of the paragraphs EPPs seek to exclude is attached to the memorandum in support of their motion to partially exclude the opinions and testimony of Dr. Trish as Exhibit 1. EPPs' Mem. Supp. Mot. Partially Exclude Opinions and Test. Trish Ex. 1, No. 16-CM-27242 [Doc. No. 230-1]; EPPs' Mem. Supp. Mot. Partially Exclude Opinions and Test. Trish Ex. 1, No. 16-CB-27242 [Doc. No. 291-2].

conduct her own analysis of spread in these cases and that she has no basis to opine on pass through in the supply chain.

# 1. Irrelevant Material

EPPs ask the Court to exclude a subset of Dr. Trish’s opinions that they say are unreliable and irrelevant. EPPs argue that the sole purpose of this material is to shift the blame of price increases to PBMs, but that the background she relies on is either unrelated to the generic pharmaceutical industry or prejudicial. EPPs take issue with Dr. Trish’s opinions on brand rebates, events outside of the Class Period, and PBM pricing tools unrelated to the prices paid by class members.<sup>98</sup> These opinions, they argue, are not relevant to the matter at hand and should be excluded under Rule 702.

EPPs assert that brand rebates—refunds brand drug manufacturers pay to PBMs to get favorable placement for their high-priced drugs on PBM formularies—are irrelevant and lack fit because brand drugs are not at issue in this case. Post-class period materials, including potential legislation, are unreliable, according to EPPs, because the conduct and materials she relies on occurred after the Class Period. EPPs also argue that the “other” pricing tools, such as Direct and Indirect Renumeration (“DIR”)<sup>99</sup> and administrative fees,<sup>100</sup> that Dr. Trish mentions are irrelevant because they are distinct from the prices paid for clobetasol and clomipramine.

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<sup>98</sup> EPPs’ Mem. Supp. Mot. Partially Exclude Opinions and Test. Trish at 5 [Doc. No. 291].

<sup>99</sup> See Trish Clomipramine Rep. ¶ 93 (“DIR fees have come to be a catch-all term for a variety of charges PBMs impose on pharmacies after the point of sale, meaning they are not directly accounted for when processing claims. Specific terminology, types, and sizes of these fees may vary across contracts.”) (footnotes omitted).

<sup>100</sup> Trish Clomipramine Rep. ¶ 101 (“PBMs charge administrative fees to TPPs, for administering and processing claims, among other administrative services. Such fees may be set on a per claim or on a per member per month basis. As with other pricing terms, these fees are often only known to the contracting parties and may vary across contracts and over time.”) (footnotes omitted).

A witness's testimony must help the trier of fact to understand evidence offered to determine a fact at issue.<sup>101</sup> But where expert testimony is not "sufficiently tied to the facts of the case [such] that it will aid the jury in resolving a factual dispute," it must be excluded.<sup>102</sup> Further, "the court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."<sup>103</sup>

Defendants argue that Dr. Trish's opinions on each of the factors listed above bear on the generics drug industry. They argue that Dr. Trish's descriptions of the role of PBMs go to explaining their market power. Defendants assert that Dr. Trish's opinions on rebates illuminate PBM revenue streams and exemplify the complexity and opacity of the industry. The Court finds that these opinions are either irrelevant to the present matter or unduly prejudicial. First, the Court agrees with EPPs that brand drug rebates are not relevant in this litigation and discussion of those rebates is likely to confuse a potential jury. Defendants, generic drug manufacturers, do not pay rebates to PBMs for generic drugs. In fact, Defendants in this matter have confirmed that they did not pay rebates in connection with the bellwether drugs.<sup>104</sup> Defendants argument that rebates are related to PBM market power is too tenuously connected to establishing PBM impact on the bellwether drugs in this matter through those rebates. Similarly, Dr. Trish does not explain in her report how the "other" pricing tools she describes may have affected the actual prices of the bellwether drugs during the relevant time periods. Her opinions are thus speculative because she makes no attempt to connect these tools to the generics drug industry.

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<sup>101</sup> *Daubert*, 509 U.S. at 591.

<sup>102</sup> *See United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985).

<sup>103</sup> Fed. R. Evid. 403.

<sup>104</sup> EPPs' Mem. Supp. Mot. Partially Exclude Trish at 6 [Doc. No. 230].



Section IX of Dr. Trish's report, too, is not connected to the matter at hand. Further, it is potentially prejudicial to EPPs. The only purpose of this section in the present matter is to impart on the trier of fact that Defendants advance a negative narrative of PBMs in general. Neither Dr. Trish nor Defendants adequately close the gap of relevance between the facts listed in Section IX and the products at issue here. The Federal Trade Commission's Investigation of PBM practices, various measures taken by states, policies by private payers, and potential legislative activity are only tenuously related to the issue of determining whether PBMs could have impacted pricing for clomipramine and clobetasol in these cases. Although descriptions of each of the above actions may be relevant to a discussion of the broader regulatory and enforcement environment for PBMs, those unrelated initiatives are significantly more likely to be more prejudicial and confusing to the fact finder than they are to be illuminating in this matter.

Thus, descriptions of brand rebates, post-conspiracy materials, and other pricing tools in Dr. Trish's report, and any other testimony describing the content therein, are excluded from these cases.

## 2. Opinions on Spread Pricing

EPPs argue that Dr. Trish's opinions on spread pricing are methodologically unsound and must be excluded. EPPs argue that Dr. Trish "avoids performing any analyses that might support her opinions and, even when she undertakes them, her methodologies are fundamentally flawed."<sup>105</sup> According to EPPs, these critical errors are that Dr. Trish: (1) opines on PBM profits without analysis on whether changes in PBM concentration, complexity, or price opacity had any actual impact on clobetasol and clomipramine prices; (2) opines that spread pricing increased

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<sup>105</sup> EPPs' Mem. Supp. Mot. Partially Exclude Trish at 2 [Doc. No. 230].

during the Class Period but does not perform any calculations on which to ground her opinions; and (3) does not perform modeling or statistical analysis on end-payer costs.

Dr. Trish seeks to discredit the reports of multiple experts for EPPs. But to do so, she must still provide good grounds based in the methods and principles of scientific analysis.<sup>106</sup> Further, even where an expert has offered good grounds for their opinion, that court may yet “conclude that there is too great an analytical gap between the data and the opinion proffered” if the expert’s opinions do not flow from their facts presented.<sup>107</sup>

Here, there is too large a gap between Dr. Trish’s presented data and her opinions critiquing EPPs’ experts. Where Dr. Trish uses theories that PBMs have leveraged consolidation, complexity, and opacity to increase end-payer drugs costs and their own profits to critique EPPs’ experts, she must provide a reliable analysis to connect those issues to the facts of this case. It is not enough for her to contend that her own expertise and outside material demonstrate that PBMs have “leveraged the complexity, opacity, and consolidation of the pharmaceutical supply chain”<sup>108</sup> in general. She must, if she argues that those factors have bearing in this case, analyze the effects of those factors on the bellwether products at issue to adequately discredit EPPs’ experts.

In her report, Dr. Trish opines in one instance that “[i]ncreased PBM spreads may correspond to an increase in end payor costs, or alternatively, they may correspond to instances in which the PBM’s reimbursement to the pharmacy declined, but those savings were captured by the PBM and not the end payor.”<sup>109</sup> But because Dr. Trish uses this example, and others like

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<sup>106</sup> See *Paoli*, 35 at 732.

<sup>107</sup> See *In re TMI Litig.*, 193 F.3d 613, 682 (3d Cir 1999), *as amended*, 199 F.3d 158 (3d Cir. 2009).

<sup>108</sup> See Trish Clomipramine Rep. ¶ 111.

<sup>109</sup> Trish Clomipramine Rep. ¶152 (citation omitted).

it, to assert that Dr. McClave has overstated his estimated damages, it is incumbent upon her to conduct analysis to demonstrate if and how PBMs did actually capture that profit. Further, Dr. Trish's opinions on overcharge pass through and that Defendants' price increases flowed from PBMs, and not from the manufacturers' alleged price increases, requires further analysis. Unless Dr. Trish can demonstrate that complexity, consolidation, profits, and pass-through had a direct tie to the cost of clobetasol and clomipramine, her opinions are impermissibly speculative.<sup>110</sup> While she shows with abundant literature that all factors affect the pharmaceutical industry, the gap between her findings and these products remains too large.

Dr. Trish's assignment was to "to analyze and explain the generic drug supply chain and its stakeholders, including the pricing of generic drugs at those different levels throughout the supply chain" and "analyze the role of intermediaries, so, for example, pharmacies and PBMs, in terms of how they determine the prices or how they impact the prices paid by end-payers for generic drugs, specifically for the two at-issue products for these matters, so the clomipramine and clobetasol products."<sup>111</sup> The opinions she expresses in her critique of EPPs' experts, however, have no reliable basis for the reasons stated above. Thus, Dr. Trish's opinions on spread pricing are excluded.

EPPs' motion to partially exclude Dr. Trish's opinions is granted.

#### **D. Dr. Russell L. Lamb**

Dr. Russell L. Lamb is the EPPs' expert on whether common evidence suggests the existence of the alleged conspiracy and, if so, to what extent common evidence demonstrates that members of the proposed classes were injured by paying supracompetitive prices. Dr. Lamb is

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<sup>110</sup> *Paoli*, 35 F.3d at 742 (expert testimony does not have good grounds if subjective or speculative).

<sup>111</sup> Tr. of Daubert Hr'g (Sept. 26, 2024) at 12 [MDL Doc. No. 3112].

the President and co-founder of Monument Economics Group, an economics consulting firm. He holds a Ph.D. in economics from the University of Pennsylvania and has published peer-reviewed research in journals related to economics.<sup>112</sup> Defendants do not question Dr. Lamb's credentials.

Dr. Lamb describes the pharmaceutical supply industry and explains the impact of WAC on end-payer costs. Importantly, he argues that list prices directly affect the amount paid by a TPP regardless of the exact methodology used to determine the reimbursement amount. To analyze the relationship between WAC and EPP drug costs, Dr. Lamb performed a multiple regression analysis. Analyzing a 100 percent increase in WAC, Dr. Lamb found an 89 to 95 percent increase in EPP drug costs for clomipramine<sup>113</sup> and 55 to 82 percent increase for various formulations of clobetasol.<sup>114</sup> Dr. Lamb makes two primary findings: (1) that common economic evidence—including structural characteristics of the market and the economic performance of the generic drugs—is consistent with the existence of the alleged conspiracy and is inconsistent with a market free of anticompetitive behavior; and (2) that common evidence and analysis shows that nearly all members of the proposed classes were injured as a result of the conspiracy.

Although they acknowledge his extensive background and expertise, Defendants argue that Dr. Lamb's analysis is outcome-oriented, and his methodology is unsound. Defendants move to exclude Dr. Lamb's opinions that common evidence is consistent with the existence of an alleged conspiracy to fix prices for generic clobetasol and clomipramine and that nearly all members of the proposed class were injured as a result of Defendants' misconduct.

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<sup>112</sup> Lamb Corrected Expert Report [Clomipramine], Bank Decl., Ex. 1, ¶¶ 1-5 [Doc. No. 199-4] (hereinafter "Lamb Clomipramine Rep."); Bank Decl., Ex. 14, Lamb Corrected Expert Report [Clobetasol], Bank Decl., Ex. 1, at ¶¶ 1-5 [Doc. No. 254-3] (hereinafter "Lamb Clobetasol Rep.>").

<sup>113</sup> Lamb Clomipramine Rep. ¶40.

<sup>114</sup> Lamb Clobetasol Rep. ¶44.

# 1. Common Evidence Reliability

## *Structure-Conduct-Performance Paradigm*

Defendants argue that Dr. Lamb’s fundamental flaw lies in his use of the Structure-Conduct-Performance (“SCP”) Paradigm because it “cannot differentiate oligopoly conduct from anticompetitive conduct. . . .”<sup>115</sup> The SCP Paradigm is an approach in antitrust analysis that economists use to link structure, conduct, and performance to market structure and to predict whether concentration will facilitate (tacit or explicit) collusion and that as barriers to entry rise, the “optimal price-cost margin of the leading firm or firms likewise will increase.”<sup>116</sup> Defendants allege that the SCP Paradigm is irregular and unaccepted in the field of antitrust economics, and further unhelpful when applied to an oligopolistic market. In contrast, the EPPs argue that the SCP Paradigm remains a reliable method of analysis that courts regularly affirm expert testimony on the basis of consistency of certain conduct with price-fixing. EPPs argue that while Defendants cite to articles that disfavor SCP analysis, they ignore literature that finds SCP to be a reliable means of evaluating conduct. Regardless, EPPs say, academic criticisms of the SCP Paradigm are irrelevant in cases such as this where there is direct evidence of express collusion.

The Court agrees with EPPs that, although the SCP Paradigm appears disfavored among certain schools of economists and does not appear to be a particularly popular methodology, courts have routinely found it useful in antitrust analyses. In *In re Processed Egg Products*, the court found the testimony of an expert examining conduct and collusion as admissible, citing another court that had determined that the “[s]tructure -conduct-performance analysis by an economist is well-accepted in this field, and the [c]ourt concludes that it would be helpful to a

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<sup>115</sup> Defs.’ Mem. Supp. Mot. Exclude Lamb at 9 [Doc. No. 199].

<sup>116</sup> Leonard W. Weiss, *The Structure-Conduct-Performance Paradigm and Antitrust*, 127 U. Pa. L. Rev. 1104 (1979).

jury for an expert to put events into an economic context.”<sup>117</sup> The *Processed Egg Products* court further concluded that expert testimony may be helpful to the trier of fact where antitrust legal theory is inextricably linked with economic theory.<sup>118</sup> Other courts have also held that the SCP Paradigm is a valid methodology that courts have accepted in the past.<sup>119</sup>

Defendants argue that the SCP Paradigm was not designed to distinguish whether higher than normal prices were the result of collusion. Dr. Lamb, however, relies on a multitude of record information to determine that collusion occurred, including admissions from Mr. Bahari, but also including Mr. Kellum’s guilty plea, DPAs from Sandoz and Taro, and testimony from additional employees. Importantly, in his deposition, Dr. Lamb testified that while he draws from the SCP Paradigm, his methodology stands on its own and incorporates other modes of analysis:

“Well, I think [the SCP Paradigm] provides a useful framework for thinking about whether there is a cartel in a marketplace. When one thinks about the [] conduct prong of that discussion in particular, when conduct includes exchanging confidential business information and exchanging price lists and declining to compete for business and so forth, it certainly informs that question.

But [] I would be careful in thinking about the textbook treatment as more than just [] an approach that others have taken in thinking about how to analyze competition in a marketplace.

And my reports are my reports....It's organized in the Structure-Conduct-Performance paradigm, but it could be organized in other ways, I think, and reach the same conclusions.”<sup>120</sup>

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<sup>117</sup> *In re Processed Egg Prods. Antitrust Litig.*, 81 F. Supp. 3d 412, 424–25 (E.D. Pa. 2015) (quoting *In re Urethane Antitrust Litig.*, No. 04-1616, 2012 WL 6681783 (D. Kan. Dec. 21, 2012), *aff'd*, 768 F.3d 1245 (10th Cir. 2014)).

<sup>118</sup> *Id.* at 425.

<sup>119</sup> *In re Urethane Antitrust Litig.*, 152 F. Supp. 3d 357, 361 (D.N.J. 2016) (citing *Kleen Prods. LLC v. Int'l Paper*, 306 F.R.D. 585, 598 (N.D. Ill. 2015), *aff'd*, 831 F.3d 91 (7th Cir. 2016); *TC Systems Inc. v. Town of Colonie, New York*, 213 F. Supp. 2d 171, 182–83 (N.D.N.Y. 2002)).

<sup>120</sup> Defs.’ Mem. Supp. Mot. Exclude Lamb, Bank Decl., Ex. 3, Lamb Dep. Tr. Jan 5, 2024 at 241, 16-CM-27242 [Doc. No. 199-5]; Defs.’ Mem. Supp. Mot. Exclude Lamb, Bank Decl., Ex. 3, Lamb Dep. Tr. Jan 5, 2024 at 241, 16-CB-27242 [Doc. No. 254-5] (hereinafter “Lamb Dep.”).

Dr. Lamb's methodology is not unreliable just because he draws on a paradigm that has been disfavored in some circumstances. Defendants' attacks on his methodology may go to the weight of his opinions, but Dr. Lamb offers good grounds, including his experience and examples of conduct, to draw on the SCP Paradigm to reach his conclusions.

#### *Evidence Review*

Next, Defendants argue that Dr. Lamb did not employ reliable methodology for reviewing record evidence, arguing that he provided little description of his methodology to review record evidence outside of searching a database for keywords.<sup>121</sup> Dr. Lamb indicates that he has rested his opinions on his own research into the markets for clobetasol and clomipramine, his review of discovery in this litigation, economic literature, and his own training in the relevant fields. EPPs counter that Defendants' argument that Dr. Lamb "cherry-picked" his evidence has no merit and that his review was appropriately comprehensive.

In *In re Processed Egg Products*, the trial court rejected Defendants' motion to exclude the testimony of an expert on the basis that he had not considered all facts in the record where evidence in the case was voluminous: "Finally, the Court rejects Defendants' contention that [the expert's] testimony should be excluded because he failed to consider certain aspects of the record. The briefing and arguments have not revealed that [the expert's] failure to include certain facts in his analysis was so egregious as to make his methodology unreliable. This contention goes to the weight of [the expert's] testimony, not its admissibility. The record in this case is voluminous, to say the least, and no expert will be able to include every document in his

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<sup>121</sup> Defs.' Mem. Supp. Mot. Exclude Lamb at 10 [Doc. No. 199].

analysis.”<sup>122</sup> Further, the existence of some contradicting evidence is not necessarily a basis on which to exclude an expert’s testimony.<sup>123</sup>

Similarly, the record is voluminous in this matter. Dr. Lamb examined millions of documents in this case to form his opinions and his use of key words to narrow his review to relevant documents is far from outside the norm.<sup>124</sup> Defendants cite portions of deposition testimony in which various witnesses deny knowledge of agreements with certain competitors. EPPs argue that these examples do not challenge Dr. Lamb’s findings because, as Dr. Lamb argues, “one would not expect every employee of a conspiring Defendant to know every detail of the conspiracy.”<sup>125</sup>

In his deposition, Dr. Lamb explained that “testimony admitting the existence of agreements, admitting conversations, the exchange of confidential business information, is consistent with evidence that” prices rose dramatically.<sup>126</sup> Evidence that certain witnesses deny being party to agreements with certain firms, however, does not diminish his confidence in his findings because firms may make agreements to raise prices with another firm without knowledge about conversations or agreements taking place between other firms in the marketplace.<sup>127</sup> For example, Defendants cite to the deposition testimony of a former Sandoz executive, Chris Bihari, that they say contradicts Dr. Lamb’s findings.<sup>128</sup> In Dr. Lamb’s

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<sup>122</sup> *Processed Egg Prods.*, 81 F. Supp. 3d at 425.

<sup>123</sup> *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012).

<sup>124</sup> Lamb Dep. at 185.

<sup>125</sup> EPPs’ Mem. Opp. Mot. Exclude Lamb at 15, No. 16-CM-27242 [Doc. No. 223]; EPPs’ Mem. Opp. Mot. Exclude Lamb at 15, No. 16-CB-27242 [Doc. No. 285].

<sup>126</sup> Lamb Dep. at 534 [Doc. No. 199-5].

<sup>127</sup> *Id.* at 535-36.

<sup>128</sup> Defs.’ Mem. Supp. Mot. Exclude Lamb at 10-11 [Doc. No. 199].



deposition, he was read a quote in which Mr. Bihari testified that he did not “believe” that he had entered into an agreement with Hi-Tech Pharmacal Co. to raise the price of clobetasol.<sup>129</sup>

Although Dr. Lamb had not considered that particular quote in his analysis, he explained that it did not change his views because Mr. Bihari was just one employee of a single Defendant manufacturer who was unlikely to be privy to all conversations between Defendants regarding every aspect of the alleged conspiracy: “[i]t is not surprising to find that one person employed by one Defendant in an allegation of anticompetitive conduct doesn't know everything there is to know about a cartel. That’s just not surprising.”<sup>130</sup> According to Dr. Lamb, affirmative evidence that one has admitted to certain conduct is more probative than evidence that an individual is unaware that certain conduct occurred.<sup>131</sup>

Likewise, Dr. Lamb explains that other examples from Defendants in which individuals denied knowledge of a conspiracy do not change his opinions. For example, Defendants argue that Dr. Lamb ignored evidence that Michael Vezza, former Associate Director of Pricing & Analysis at Sandoz, denied that Mylan and Sandoz had conspired on clomipramine.<sup>132</sup> The excerpt they read Dr. Lamb in his deposition, however, does not bear out the extremes they pose in their motion. Instead, Mr. Vezza’s transcript reflects only that he did not recall whether he had any personal knowledge of any agreements between Sandoz and Mylan to allocate customers or fix prices.<sup>133</sup>

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<sup>129</sup> Lamb Dep. at 541-42.

<sup>130</sup> *Id.* at 543.

<sup>131</sup> *Id.* at 540-41.

<sup>132</sup> Defs.’ Mem. Supp. Mot. Exclude Lamb at 11 [Doc. No. 199].

<sup>133</sup> Lamb Dep. at 306.

In his report, Dr. Lamb includes admissions and evidence from a number of witnesses' testimony to support his contention that Defendants' conduct was consistent with conspiracy.<sup>134</sup> Dr. Lamb states that his purpose is to offer examples of "[b]ehavior or conduct that would be contrary to an individual firm's unilateral economic self-interest in the absence of an anticompetitive agreements... ." <sup>135</sup> He provides numerous examples to ground his opinions on the matter of conduct. Dr. Lamb explains in his deposition that the pieces Defendants point to that he did not consider are "one piece of evidence" that, in his opinion, are outweighed by the culmination of all of the other evidence he cites in his report to demonstrate that Defendants' conduct was indeed consistent with collusion.<sup>136</sup>

The Court agrees with EPPs that Dr. Lamb need not have reviewed or cited to every, or most, documents on the record, given the volume of discovery in these cases. Moreover, Dr. Lamb has offered his opinion that individual examples of a witness denying part or knowledge in one aspect of a conspiracy does not necessarily disprove a broader scheme.<sup>137</sup> This goes to the weight, not the validity, of his opinions. Dr. Lamb has sufficiently good grounds to claim that, based on his entire view of the record, none of these supposed omissions in the data are reflective of the record as a whole.

Dr. Lamb's analysis is unlike the problematic expert analysis in *In re Zolof (Sertraline Hydrochloride) Product Liability Litigation*, a products liability case in which this Court excluded an expert opinion that failed to adequately account for scientific evidence that directly

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<sup>134</sup> See e.g., Lamb Clobetasol Rep. at ¶¶ 53-55; Lamb Clomipramine Rep. at ¶¶ 51-53, 59.

<sup>135</sup> Lamb Clomipramine Rep. at ¶ 50.

<sup>136</sup> Lamb Dep. at 302.

<sup>137</sup> Lamb Dep. at 500-01.

contradicted her findings.<sup>138</sup> In that case, an expert opining on causation impermissibly neglected to consider information, including some of her own peer-reviewed studies, that may have greatly affected the outcome of her methodology.<sup>139</sup> Causal conclusions require examination of the literature of a field as a whole, but the expert in *Zoloft* neglected to include concerning swaths of pertinent literature. The omitted evidence, if included, may have drastically changed that expert's opinions. The present matter is quite different. Here, Dr. Lamb's scientific evidence is not at issue. Instead, Dr. Lamb has reviewed an abundance of record evidence on which he forms his opinions. The evidence that he does not include does not materially affect his findings as stated above.

In the present case, Dr. Lamb has presented good grounds on which to base his opinions and the evidence he did not include does not materially affect his opinions for the reasons stated above. Dr. Lamb's methodology on this point is not unreliable.

### *Oligopoly*

Defendants further question the reliability of Dr. Lamb's opinions on common evidence because they indicate that his opinions do not offer a methodology to distinguish between a legal oligopolistic market functioning normally and an illegal oligopolistic market functioning under collusive agreements. Defendants claim that Dr. Lamb's report relies on circular reasoning by "assuming as true what he was tasked with proving: that the observed increased WACs for clobetasol and clomipramine were caused by collusion."<sup>140</sup> EPPs counter that Dr. Lamb's analysis expressly considers oligopoly through a comprehensive review of the evidentiary

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<sup>138</sup> 26 F. Supp. 3d 449 (E.D. Pa. 2014).

<sup>139</sup> *Zoloft*, 26 F. Supp. 3d at 460.

<sup>140</sup> Defs.' Mem. Supp. Mot. Exclude Lamb at 16 [Doc. No. 199].

record. According to Dr. Lamb, communications between rival firms can distinguish a cartel from oligopolistic interdependence.<sup>141</sup>

Dr. Lamb provides good grounds for his opinion that the conduct between Defendants was beyond tacit collusion. At this stage, that is all he is required to do. Defendants' reliance on the decision in *Valspar Corp. v. E.I Du Pont De Nemours & Co.* is premature, as the discussion in that case describing the "special problem" in distinguishing between legal oligopoly and cartel behavior was in the context of summary judgment, not *Daubert*.<sup>142</sup> Defendants' reliance on the decision in *In re Chocolate Confectionary Antitrust Litigation* for the proposition that communications between firms is not necessarily sufficient to support the inference of a conspiracy is misplaced.<sup>143</sup> In that case, the Third Circuit more specifically held in the context of summary judgment that "sporadic communications" infrequently over the course of three years was not enough to create such an inference.<sup>144</sup> Dr. Lamb cites evidence of more than "sporadic" communications in his report, which is sufficient for *Daubert* purposes.

Dr. Lamb's opinions on collusion, as they relate to both common evidence and common impact, are reliable. To the extent that Defendants find that oligopolistic behavior is a more probable explanation for the conditions that he describes in his report, those criticisms go to the weight of his opinions.

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<sup>141</sup> EPPs' Resp. Opp'n Mot. Exclude Lamb, No. 16-CM-27242 [Doc. No. 223] at 17; EPPs' Resp. Opp'n Mot. Exclude Lamb, No. 16-CB-27242 [Doc. No. 285] at 17; Lamb Clomipramine Reply Report, EPPs' Resp. Opp'n Mot. Exclude Lamb, Ex. 7 [Doc. No. 223-7] ¶¶ 11-15; Lamb Clobetasol Reply Report, EPPs' Resp. Opp'n Mot. Exclude Lamb, Ex. 6 [Doc. No. 285-6] ¶¶ 11-16.

<sup>142</sup> 873 F.3d 185, 191 (3d Cir. 2017).

<sup>143</sup> 801 F.3d 383, 409 (3d Cir. 2015).

<sup>144</sup> *Id.* at

## 2. Common Impact Reliability

### *Use of Averaging*

Defendants argue that Dr. Lamb’s opinions on the positive relationship between list prices and end-payer prices are faulty because they confuse correlation with causation.

Defendants take issue with Dr. Lamb’s analysis because they allege it can only show that “that list prices for clobetasol and clomipramine increased, and some other prices (but not all) in the pharmaceutical pricing chain increased for some (but not all) purchasers at some (but not all) times” without any causal linking relationship between those list prices and end-payer costs.<sup>145</sup>

Defendants also take issue with Dr. Lamb’s use of averages in his analysis showing trends between prices.<sup>146</sup>

As stated above, in *Lamictal*, the Third Circuit determined that a court considering class certification must perform a “rigorous analysis” of an expert’s use of averaging to determine whether the use of averages is acceptable to certify class.<sup>147</sup> The use of averaging in data may be most delicate in an industry characterized by many individualized negotiations.<sup>148</sup>

The Third Circuit in *Lamictal* reversed class certification because it found that the district court had not performed the necessary “rigorous analysis” to determine that the plaintiffs’ use of averages was acceptable.<sup>149</sup> Dr. Lamb was an expert in that case and used average prices relying on “general forecasting documents,” not product-specific prices.<sup>150</sup> Dr. Lamb’s analysis here

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<sup>145</sup> Defs.’ Mem. Supp. Mot. Exclude Lamb at 20 [Doc. No. 199].

<sup>146</sup> *Id.* at 6.

<sup>147</sup> *Lamictal*, 957 F.3d at 194.

<sup>148</sup> *Lamictal*, 957 F.3d at 193.

<sup>149</sup> *Lamictal*, 957 F.3d at 193-94.

<sup>150</sup> *Id.*

goes beyond his work in *Lamictal*. In the present matter, Dr. Lamb conducted a regression analysis using PBM data on prices for generic clobetasol and clomipramine:

Using the PBM data on prices paid for generic Clomipramine, I regressed the natural log of the weighted average end-payer drug cost (i.e., the total amount paid by the TPP and the member net of dispensing fees and taxes) for generic Clomipramine on the median WAC. I repeated this analysis for each cost basis. As shown in the table below, the correlation between WAC and the end-payer drug cost ranges from 0.97 to 0.99. The estimated coefficient on WAC is positive and statistically significant for each cost basis. For generic Clomipramine, my regression analysis finds that a 100 percent increase in WAC corresponds to an 89 to 95 percent increase in the end-payer drug cost per extended unit.<sup>151</sup>

Defendants' reliance on *Lamictal* is premature. *Lamictal* reversed class certification on grounds that the district court should have conducted a thorough analysis of competing expert opinions but did not exclude Dr. Lamb's opinions or suggest that they should have been excluded. Here, Defendants' criticisms go to the weight of his opinions and do not undermine the reliability of his model.

#### *Pricing Structure*

Dr. Lamb finds that common evidence demonstrates that a "pricing structure" exists in the market for clobetasol and clomipramine. According to Dr. Lamb, when there is a pricing structure in a market, prices paid by purchasers for a product—or interchangeable products from different sellers—tend to move together over time in response to common economic factors.<sup>152</sup> Dr. Lamb explains, "[t]his means that any economic force that generally affects the price of a given product, such as the alleged conspiracy, would result in all or nearly all purchasers of that product paying a higher price than they otherwise would have paid."<sup>153</sup> Accordingly, the presence of a price structure in the bellwether drugs market means that drug costs for those drugs

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<sup>151</sup> Lamb Clomipramine Rep. ¶ 40 (footnotes omitted).

<sup>152</sup> See Lamb Clomipramine Rep. at ¶ 174.

<sup>153</sup> Lamb Clomipramine Rep. at ¶ 174.

tend to move together, even if the costs by individual members of the proposed classes differ at any particular point in time: “[i]f there is a pricing structure, it is unlikely that any members of the proposed Clomipramine Classes could have avoided paying at least some prices that were artificially inflated by the alleged conspiracy during the Clomipramine Conspiracy Period....This means that a factor that inflates prices generally, such as the alleged conspiracy, would have affected the drug costs paid by all or nearly all members of the proposed [classes].”<sup>154</sup>

Defendants call this a “faulty mechanism” for proving common injury because it can only suggest that there is a general process for negotiation with buyers in which the parties use a list price as a reference point. Further, Defendants argue that Dr. Lamb’s pricing structure opinions eschew analysis of individual contracts.<sup>155</sup> To demonstrate the flaw in Dr. Lamb’s argument, Defendants contend that Dr. Lamb’s analysis cannot account for supposed non-injured purchasers of clomipramine. EPPs counter that Dr. Lamb’s analysis shows a positive and statistically significant relationship between list prices and the prices that TPPs paid for the bellwether drugs. EPPs also contend that Defendants do not support their argument that individual analysis of contracts is necessary in this case, and they emphasize that whether there are uninjured purchasers of clomipramine is in dispute between the parties.

Dr. Lamb’s consideration of pricing structure is just one element of his overall analysis on impact. He does not rest on this analysis alone to support his argument that common evidence demonstrates injury. To support his finding that the evidence evinces a pricing structure, Dr. Lamb cites various documents and testimony produced in this litigation. Further, he conducts empirical analyses that includes figures to demonstrate correlations between pharmacy

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<sup>154</sup> Lamb Clomipramine Rep. at ¶ 174, 193.

<sup>155</sup> Defs.’ Mem. Supp. Mot. Exclude Lamb at 21 [Doc. No. 199].

acquisition costs and end-payer costs and that end-payer costs correlate to changes in WAC over time. Defendants indicate that Dr. Lamb’s methodology is flawed because it cannot account for one uninjured pharmacy chain.<sup>156</sup> But as EPPs argue in their briefing, whether the pharmacy is uninjured is in dispute between the parties. Defendants’ criticisms of Dr. Lamb’s pricing structure finding goes to the weight of his testimony in class certification but does not render his opinion unreliable here.

#### **E. Ms. Laura R. Craft**

Ms. Laura R. Craft is the EPPs’ expert on the criteria for class membership, methods to establish member eligibility, and available data in the prescription drug industry to support this process. Ms. Craft is the president of OnPoint Analytics, Inc., an economical, statistical, and financial consulting firm specializing in data analytics for complex litigation. She holds a Master of Public Health degree from the University of California, Berkeley and a law degree from the University of California, Hastings. Since 2004, she has overseen the firm’s work regarding pharmaceutical products, including more than 65 pharmaceutical matters.<sup>157</sup> Defendants do not challenge Ms. Craft’s credentials.

Ms. Craft presents six separate opinions: (1) that the nature of the generics industry results in intense price competition; (2) that transactional data in the pharmaceutical industry is uniquely reliable and robust; (3) that data from PBMs provide an authoritative record of class purchasers; (4) that third party payer class members keep detailed receipts of prescription drugs purchases; (5) that excluded TPPs are easy to identify and can be removed from data used to

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<sup>156</sup> *Id.*

<sup>157</sup> Craft Corrected Expert Report [Clomipramine], Moskowitz Decl. Ex. 1 ¶¶ 3-10, No. 16-CM-27242 [Doc. No. 200-3] (hereinafter “Craft Clomipramine Rep.”); Craft Corrected Expert Report [Clobetasol], Moskowitz Decl. Ex. 1 ¶¶ 3-10, No. 16-CB-27242 [Doc. No. 255-3] (hereinafter “Craft Clobetasol Rep.”).



calculate damages; and (6) that the claims administration process will confirm that only proper class members participate.

Defendants move to exclude Ms. Craft's opinion in its entirety. Defendants raise three primary arguments to support their motion to exclude Ms. Craft. First, they argue that Ms. Craft did not employ a reliable methodology in her analysis for establishing class member eligibility and did not specify a source of data to support TPP claims. Next, they argue that Ms. Craft's assertion that PBM data is sufficient to identify non-class purchases for exclusion is hampered by data on the record. Finally, Defendants say that Ms. Craft did not conduct reasonable analysis that the Standardized PBM data demonstrates that there is a "mechanical link" between WAC prices and various cost bases underlying prices paid by TPPs.<sup>158</sup> Each argument is considered below.

#### I. Class Member Methodology

Defendants argue that Ms. Craft did not put forth a reliable methodology to establish class member eligibility and did not specify a source of data to support TPP claims. Instead, they argue that she has described a process through which TPPs will present their own data and attest to their own class certification. Defendants argue that TPPs are unlikely to know how to accurately interpret transactional claim data. Her analysis, Defendants argue, does not constitute a "testable methodology through which any list of TPPs" can be developed.<sup>159</sup> Thus, they contend that Ms. Craft's opinions are insufficient for EPPs to ascertain class.

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<sup>158</sup> Defs.' Mem. Supp. Mot. Exclude Craft at 24, No. 16-CM-27242 [Doc. No. 200]; Defs.' Mem. Supp. Mot. Exclude Craft at 24, No. 16-CB-27242 [Doc. No. 255].

<sup>159</sup> Defs.' Mem. Supp. Mot. Exclude Craft at 16-17 [Doc. No. 200].

Defendants point to *In re Niaspan Antitrust Litigation*<sup>160</sup> to contend that Judge DuBois rejected a similar methodology offered by Ms. Craft using the “same data.”<sup>161</sup> In *Niaspan*, however, Judge DuBois *accepted* Ms. Craft’s expert testimony for the purposes of *Daubert* but denied *class certification* on the basis that EPPs had not met their burden to prove a reliable method of identifying class members without more information about Ms. Craft’s process. In her testimony in this case, Ms. Craft addressed her opinions in *Niaspan* and the suggestion that her opinions in this matter are “the same” as her opinions in that case, explaining:

[I]t’s just flatly incorrect that this is the same fact pattern or the same case as presented in *Niaspan*. *Niaspan* addressed a very specific question, and that was whether a list of all potential class members could be generated by looking at PBM data that had been produced in bulk, and nothing else.

It presumed that there was no recourse to other information to generate that list, and that a list with names was required at that point in the process prior to class certification.

...

[Here] what I was asked to do had really two functional parts. And the first was to help compile this very large data set that the Court has already heard about, coming from PBMs that provides transactional detail about many millions of purchases of the class products. And the second was that I was asked to answer the question, can class members here provide data and authoritative business records that confirm their eligibility to participate in the class? Very, very different question than *Niaspan*.<sup>162</sup>

The situation in the present matter, Defendants say, is “worse” than her testimony in *Niaspan* in that, here, she has not offered a list or method by which class members could be systematically identified. Defendants argue instead that Ms. Craft only implies the existence of reliable information, but not an administratively feasible methodology in which to utilize that data to identify class members.

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<sup>160</sup> 464 F. Supp. 3d 678 (E.D. Pa. 2020).

<sup>161</sup> Defs.’ Mem. Supp. Mot. Exclude Craft at 3 [Doc. No. 200].

<sup>162</sup> Tr. of Daubert Hr’g (Sept. 25, 2024) at 14-15 [MDL Doc. No. 3111]. *See also Niaspan*, 464 F. Supp 3d at 695.

EPPs argue that whether Ms. Craft’s opinions are sufficient to show that classes are ascertainable is not at issue in the current motion, her reliability is. Further, EPPs argue that Defendants cite to no precedent for their suggestion that Ms. Craft must create a “list” of TPPs and have not explained why they think it unlikely that TPPs would be able to find purchase receipts through “various sources.”<sup>163</sup> Regarding interpretation of transactional data, EPPs argue that TPPs are well suited to know if they are potential class members, that there is only one TPP per transaction (minimizing confusion), and that Defendants have not identified a field for which interpretation will be an issue.

An expert must demonstrate that their opinions are founded on “good grounds.”<sup>164</sup> At the *Daubert* stage, EPPs are not required to prove that they can ascertain class based on Ms. Craft’s opinions, they need only demonstrate that those opinions are reliable.<sup>165</sup>

First, Defendants’ reliance on the decision in *Niaspan* is misplaced in this stage of litigation. In the present case, Defendants have not demonstrated that Ms. Craft’s methodology is “worse” than the methodology Judge DuBois approved in *Niaspan*. Nor have they shown that her methodology here is so like the flawed methodology at class certification in *Niaspan* that it must be excluded.

Further, Ms. Craft’s opinions are not unreliable even if they cannot, standing alone, prove EPPs’ argument on ascertainability. Ms. Craft is presented as an expert on class membership and need only provide good grounds for her opinions for which she was offered. She is not required to put forth a methodology for ascertainability, which is EPPs’ burden to prove at a later stage in

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<sup>163</sup> EPPs’ Opp’n Defs.’ Mot. Exclude Craft at 6, No. 16-CM-27242 [Doc. No. 224]; EPPs’ Opp’n Defs.’ Mot. Exclude Craft at 6, No. 16-CB-27242 [Doc. No. 287].

<sup>164</sup> *Paoli*, 35 F.3d at 744–45.

<sup>165</sup> *Id.* at 743.

litigation. Here, Ms. Craft provides good grounds to support the reliability of her opinions from which EPPs may draw to demonstrate ascertainability at class certification. Ms. Craft describes her process in these cases in her testimony:

Q But if you didn't create a list of class members, what did you do?

A I carefully analyzed the data and other authoritative business records that are available to class members, to TPPs, to determine whether that information was sufficient to confirm their eligibility for the class.

...

Q Okay. And is this opinion based on the data produced by PBMs in this litigation that we were discussing earlier?

A No. It's based [on] more on that. It's based on the information available to TPPs themselves.

Q But hold on. Hold on. Wait a minute. Didn't the TPP data that you've been talking about originally come from the PBMs? So why would it make any difference if the TPP produced it or if we're talking about the PBM data for the data set?

A So one of the key things that defendants focus on when they look at the PBM data is they say I don't always see the name spelled out for the particular TPP. I know there is one, but I don't always see their name spelled out. It might be a code number. . . .

TPPs know the answer to this question. And when they present their data, they will be supplying their names, presumably their tax ID numbers, information that they can supply any time, today, tomorrow, five years from now.

Q And how do you know that TPPs have or can obtain those receipts that detail their purchases?

A Well, the fulsome discovery record in this case helps to confirm that. We have nine named plaintiffs between the two drugs, and they all were able to produce all of their transactional data for clobetasol and clomipramine purchases dating back before the commencement of the class period.

Q And was there a process that you followed in determining whether TPPs could supply records of their class purchases?

A There was. I went through the process of trying to answer three questions. First, were authoritative records with all of this information we need created at the time of the purchase? Second, are those records currently accessible to TPP class members? And I

wanted to confirm that they were. And third, can those particular records be used to prove membership in the class?<sup>166</sup>

As demonstrated in her testimony, Ms. Craft presents a process through which EPPs can assess individual payers for class membership eligibility. Defendants criticize her opinions and argue that her methods would allow TPPs to produce unspecified claims data and that that data could be what was “most convenient for the . . . class member.”<sup>167</sup> However, Ms. Craft clarified in her testimony that, because TPPs may have multiple sources from which they are *able* to retrieve data, they will be able to do so in the method that is easiest, or more convenient for them—not that they would be able to produce whatever *data* is most convenient for them.<sup>168</sup> Presumably, even if data does not have a field in the PBM data identifying the TPP, that issue is moot when a specific TPP requests its own data from its own PBM. Ms. Craft confirms as much in her testimony.<sup>169</sup> Defendants suggest that Ms. Craft need provide more than her “say so”

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<sup>166</sup> Tr. of Daubert Hr'g (Sept. 25, 2024) at 36-37 [MDL Doc. No. 3111].

<sup>167</sup> Defs.' Mem. Supp. Mot. Exclude Craft at 2 [Doc. No. 200].

<sup>168</sup> Q . . . “A So what's most preferable as a source, I would imagine, is the most convenient for the class member.” You said that?

A That's right. And that is not what your question said. You asked me whether I had opined that TPPs could, I believe this is a quote, produce whatever was most convenient for them. That's totally inaccurate.

What this says is that they would produce the claims data, which they might retrieve from their own servers, or if they used an ASO, or if they used a TPA from them. No entity, no ASO or TPA. If they've got one or the other, so that's what's convenient.

. . .

Q Thank you. If the TPP did not have its own records, they could submit PBM data, correct?

A It could request the data from the PBM for its claims and its alone and submit that.

Tr. of Daubert Hr'g (Sept. 25, 2024) at 79-80 [MDL Doc. No. 3111].

<sup>169</sup> Q If the PBM data has the shortcomings that the courts in this circuit have repeatedly identified, isn't it true that those same shortcomings would be presented to us if the TPP collected PBM data and submitted PBM data? The PBM data itself?

A No, it's not.

Q Okay. Is it a different set of PBM data that these claimants would be collecting than the PBM data that was at issue in *Niaspan*? Is there some other PBM out there, PBM data?

about the existence of such records. Here, however, the availability and sufficiency of these records is based on more than speculation. Ms. Craft has conducted detailed analysis of the types of records available, put forth evidence based on her experience with these records. Further, Defendants argue that Ms. Craft does not offer an administratively feasible methodology in which to utilize that data to identify class members.

Whether Ms. Craft's information, in addition to other proof that EPPs have suggested they will offer, will be enough to satisfy the bar for class certification remains to be seen. But EPPs are correct that at the *Daubert* stage, Ms. Craft's opinions need not prove ascertainability, now was she asked to do so. Her process provides detailed descriptions on how entities can use the voluminous data produced in discovery, along with internal data and public data sources, to produce data that EPPs will find useful in ascertaining a class. The court finds that—as in *Niaspan*—Ms. Craft's opinions are reliable and fit.

## 2. Exclusions

Next, Defendants contend that Ms. Craft's opinions that she can apply exclusions within PBM data is not reliable. According to Defendants, six of the nine PBMs have provided sworn testimony that the data they provided cannot be used to identify purchases of clobetasol or clomipramine by a federal government, Medicaid plan, or state government entity.<sup>170</sup> Defendants

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A There's no other PBM out there.

Q Okay.

A But, yes, there are differences in what they would be submitting. The principal one is that the *Niaspan* court was concerned about identifying the name of the ultimate end payer as opposed to an ASO.

When this data is produced upon request to a TPP so that can be used in claim submission, I'm sure you understand that ordinarily it is going to have the name of the TPP on it, which was the point of concern. . . .

Tr. of Daubert Hr'g (Sept. 25, 2024) at 82 [MDL Doc. No. 3111].

<sup>170</sup> Defs.' Mem. Supp. Mot. Exclude Craft at 21 [Doc. No. 200].

also claim that Ms. Craft's flagging process failed to consistently exclude claims in the Standardized PBM Data set from pharmacies servicing excluded entities. EPPs counter that Ms. Craft has employed a process to filter out excluded entities. EPPs say that experts can identify the volume of transactions without the use of a specific field to identify entities and that Defendants have identified fewer than 5,000 transactions that should have been excluded out of 14.3 million clobetasol transactions and fewer than 350 transactions that should have been excluded out of 1.03 million clomipramine transactions.<sup>171</sup>

Ms. Craft has testified to her experience applying the exclusions in these cases, in which Ms. Craft made reductions to the class for certain government entities:

These are pretty standard exclusions. . . . So defendants and their subsidiaries and affiliates are excluded. So if they were paying the claims on plans for their employees, that's out. Federal governmental entities are out. State governmental entities are out. And then purchases that were made pursuant to Medicaid plans are out, as well.<sup>172</sup>

Ms. Craft removed entities by using a field that designated government payers and by using payer name.<sup>173</sup> In *Niaspan*, the court indicated that OnPoint's extensive experience applying class exclusions was sufficient to pass the *Daubert* standard:

As such, Craft's opinion that she can create a list of class members and apply the class exclusions in this case is based on her experience applying these types of exclusions to similar data in other cases. The Court determines that Craft's reliance upon her past experience applying 'these types of exclusions' provides sufficient grounds for her belief that she can do so again in this instance. Defendants' objections to Craft's assurances that she can apply the class exclusions go to the weight of her testimony and not its admissibility.<sup>174</sup>

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<sup>171</sup> EPPs' Opp'n Defs.' Mot. Exclude Craft at 14-15 [Doc. No. 224].

<sup>172</sup> Tr. of Daubert Hr'g (Sept. 25, 2024) at 26 [MDL Doc. No. 3111].

<sup>173</sup> See Craft Clomipramine Rep. ¶ 107.

<sup>174</sup> *Niaspan*, 464 F. Supp. 3d at 695 (quoting *Daubert*, 509 U.S. at 596).

Here too, Ms. Craft’s analysis of exclusion passes the *Daubert* standard. Where she failed to identify excluded entities, the effect of those mistakes on her findings were statistically insignificant.<sup>175</sup> As in *Niaspan*, Defendants’ objections to Ms. Craft’s ability to apply exclusions will go to the weight of her testimony.

### 3. WAC Analysis

Finally, Defendants argue that Ms. Craft did not conduct reasonable analysis to demonstrate that the Standardized PBM data shows that there is a “mechanical” link between WAC prices and various cost bases underlying prices paid by TPPs. Her opinions, they suggest, are outcome-driven and speculative because they can only assert that price and WAC must be linked because they trend together.

Ms. Craft uses the term “mechanical linkage” once in her reports on clobetasol and clomipramine, opining that “[t]he PBM records also demonstrate the mechanical linkage between the manufacturer list prices announced by Defendants and the end-purchase prices imposed on TPPs.”<sup>176</sup> EPPs claim that Defendants give undue focus to the word “mechanical” as used above.<sup>177</sup>

An expert’s testimony may be excluded if it is speculative and not based on any method or procedure.<sup>178</sup> Here, Ms. Craft’s report and testimony on WAC are not impermissibly

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<sup>175</sup> EPPs’ Opp’n Def.’s Mot. Exclude Craft at 13-15 [Doc. No. 224].

<sup>176</sup> See Craft Clomipramine Rep. ¶ 14.

<sup>177</sup> Q So defendants criticized you for saying I think the phrase is a mechanical linkage between list prices on the one hand and the prices paid by TPPs on the other. How do you respond to that criticism?

A I think they’ve misinterpreted what I’m saying, or at least what I meant. What I’m saying is that these prices are clearly related to each other as market prices for these products that are being sold by defendants. Maybe the word mechanical was not the best choice of words, but you can see how the pricing mechanisms facilitate that.

Tr. of Daubert Hr’g (Sept. 25, 2024) at 35 [Doc. No. 3111].

<sup>178</sup> *Paoli*, 35 F.3d at 742.



speculative. Ms. Craft's opinions on the issue are based in part on several analyses she conducted and charts showing what she purports to be the related movement of end payer costs and WAC prices.<sup>179</sup> Defendants indicate that Ms. Craft should have provided a formula that ties WAC to other prices. Even if taken as true, however, this argument goes to the weight of Ms. Craft's testimony, not its admissibility. Ms. Craft, an expert in this space, has conducted her own analysis on the issue. Her analysis of the data and her experience provide good grounds for her argument, which Defendants are free to later criticize.

Accordingly, for the reasons set forth above, the motion to exclude Ms. Craft's opinions and testimony is denied.

#### **F. Mr. Eric J. Miller**

EPPs rely on Eric J. Miller to develop a report on industry standard methods for notification to members of the TPP classes, as well as verification and processing of claims from the TPPs. Mr. Miller is the Senior Vice President of A.B. Data, a class action claims administrator that purports to be the "leading claims administrator for Antitrust and Securities Cases."<sup>180</sup> Mr. Miller has 20 years of experience in administering class actions, including 35 pharmaceutical indirect purchasers class actions involving TPPs. Mr. Miller indicates that A.B. Data routinely employs its methodologies in cases involving TPPs.<sup>181</sup>

Defendants advance two primary arguments to exclude Mr. Miller's testimony: that Mr. Miller is not qualified to opine on class membership and that Mr. Miller's methodology with

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<sup>179</sup> See Craft Clomipramine Rep. § VI.C.

<sup>180</sup> Home Page, A.B. DATA, <https://www.abdataclassaction.com/> (last visited December 2, 2024).

<sup>181</sup> Miller Decl. ¶¶1-6 [Doc. No. 233-2].

respect to both notice and claims administration is unreliable. Each of Defendants' arguments is considered in turn.

### 1. Qualifications

Defendants argue that Mr. Miller lacks the knowledge, skills, and training to opine in these cases. Further, they assert that he does not have the skills to identify fraudulent claims.

Courts have liberally interpreted the specialized knowledge requirement.<sup>182</sup> No formal degree, title, or education specialty is required for a witness to be qualified to offer an opinion for which they have specialized knowledge.<sup>183</sup>

The Court disagrees with Defendants argument that Mr. Miller is unqualified for the purpose that he has been presented. Mr. Miller possesses two decades of experience in this field and has administered more than 35 indirect purchaser actions involving TPP members.<sup>184</sup> Further, Mr. Miller has administered \$1.2 billion in class action cases involving TPP class members. His level of formal education is far beside the point—case law is quite clear that an expert's qualification can come from practical experience. Of that, Mr. Miller has plenty.

### 2. Reliability of Notice and Claims Administration Opinions

Defendants also argue that Mr. Miller's opinions are unreliable because his proposed testimony on notice is not based on tested methodologies and because Mr. Miller's reliance on his company's proprietary database is flawed and risks providing notice to non-class members.

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<sup>182</sup> See *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998).

<sup>183</sup> See *Lauria v. Nat'l RR Passenger Corp.*, 145 F.3d 593, 599 (3d Cir. 1998) (citing *Am. Tech. Res. v. United States*, 893 F.2d 651, 656 (3d Cir.1990)).

<sup>184</sup> Tr. of Daubert Hr'g (Sept. 25, 2024) at 150-51 [Doc. No. 3111].

On notice, Defendants say that Mr. Miller’s plan consists of mailing notice to addresses obtained from the Internet and Form 5500 filings—a method that they say was already rejected by the court in *Niaspan* at class certification. Further, Defendants say that Mr. Miller does not propose a reliable method on claims administration and that Mr. Miller has not suggested a reliable method for excluding fraudulent claims. His spot check method, they say, is unreliable.<sup>185</sup>

EPPs counter that Defendants conflate class notice standards with standards for ascertainability, and that the relevant question at issue for a *Daubert* motion is whether Mr. Miller’s descriptions of the industry-standard notice and claims administration practice are *reliable*—not whether they make EPPs’ case on class certification. EPPs posit that Mr. Miller’s testimony on both of these parts, notice and claims administration, will form a *portion* of their evidence to demonstrate a reliable process in which classes can be determined.<sup>186</sup> They do not suggest that they offer Mr. Miller’s opinions alone to prove ascertainability, but that his experience, knowledge, and expertise will be beneficial to the trier of fact in assessing the ultimate question of ascertainability. According to EPPs, Mr. Miller’s extensive experience, along with the process he outlines in his declaration, form good grounds to support his opinions on industry standards for notice and class certification.

An expert may provide an opinion based on specialized knowledge and practical experience, so long as the expert’s opinion is greater than the expertise possessed by “the

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<sup>185</sup> In addition, Defendants argue that Mr. Miller has no methodology for determining when a claimant is entitled to recover—which they say is why Mr. Miller’s testimony was excluded in part in *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352 (D.R.I. 2019). In that case, Mr. Miller’s testimony was excluded because he did not account for the need to apply class exclusions and was unable to distinguish between class members. *Id.* at 387.

<sup>186</sup> EPPs’ Opp’n Defs.’ Mot. Exclude Miller at 1–2, No. 16-CM-27242 [Doc. No. 225]; EPPs’ Opp’n Defs.’ Mot. Exclude Miller at 1-2, No. 16-CB-27242 [Doc. No. 286].

average layman.”<sup>187</sup> Mr. Miller’s opinions provide sufficient insight into the scope of his assignment to meet the standard under *Daubert*. Defendants argue that Mr. Miller’s opinions are unreliable because they fail to meet any factor in weighing an expert opinion under *Paoli*.<sup>188</sup> But Mr. Miller need not offer a scientifically or empirically valid methodology when he is offered not for such an analysis, but rather to opine on industry-standard methods. The factors listed by the court in *Paoli* apply to a “scientific technique or method.”<sup>189</sup> In this matter, Mr. Miller does not offer a *scientific* methodology and an inquiry into whether his methods are peer reviewed, testable, etc. is unhelpful to determining whether they are reliable. The Court here considers whether Mr. Miller possesses the requisite knowledge and practical experience to opine on industry standards.

Mr. Miller’s description of industry standards is based in his specialized knowledge and his extensive experience in matters administering notice and claims administration in class-action litigation, described *infra*. EPPs offer Mr. Miller to fulfill a narrow purpose and they are not required to show that their argument for ascertainability at class certification can be entirely satisfied on his testimony alone. Whether EPPs can specifically identify class members is not grounds to exclude Mr. Miller’s testimony, but a question that the Court will evaluate at class certification. Mr. Miller’s opinions on industry-standard methods for delivering notice and for the submission and processing of claims are thus not excluded.

Mr. Miller is qualified to offer the opinions in his report. Defendants motion to exclude the opinions of Mr. Miller is denied.

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<sup>187</sup> *Waldorf*, 142 F.3d at 625.

<sup>188</sup> See Defs.’ Mem. Supp. Mot. Exclude Miller at 12, No. 16-CM-27242 [Doc. No. 197-1]; Defs.’ Mem. Supp. Mot. Exclude Miller at 12, No. 16-CB-27242 [Doc. No. 253].

<sup>189</sup> *Paoli*, 35 F.3d at 742.

### **G. Dr. Laura E. Happe**

Defendants present Dr. Happe as an expert on pharmaceutical payment data to evaluate EPPs' claims that class members may be ascertained with data and documents provided through the class notice and claims administration process. Defendants instructed Dr. Happe "to assess and evaluate the approaches proposed by Plaintiffs to identify members of the proposed classes and eligible transactions" including the reports and opinions of EPPs' experts Ms. Craft and Mr. Miller.<sup>190</sup> Dr. Laura E. Happe is a professor at the University of Florida, College of Pharmacy, Department of Pharmaceutical Outcomes & Policy, where she is the director of a graduate program and lead faculty member for the managed care pharmacy curriculum. She was previously the Chief Pharmacy Officer of Humana and is a licensed pharmacist.<sup>191</sup>

In their motion to partially exclude Dr. Happe's testimony, EPPs present a limited challenge to Dr. Happe's opinions rebutting Mr. Miller's declaration on the basis that she is not qualified to opine on industry class notice standards and that the opinions she expresses are speculative and lack good grounds.<sup>192</sup>

To be qualified to offer an opinion, an expert must have specialized training or experience in a particular field.<sup>193</sup> Defendants offer Dr. Happe as an expert on ascertainability, and EPPs do not contest her qualifications on that subject. To the extent that Dr. Happe critiques Mr. Miller's work, Defendants argue that her opinions are appropriate because EPPs have made

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<sup>190</sup> Happe Expert Report, EPPs' Mem. Supp. Mot. Exclude Happe, Ex. 1 ¶ 16, No. 16-CM-27242 [Doc. No. 231-1] (hereinafter "Happe Clomipramine Rep."); Happe Expert Report, EPPs' Mem. Supp. Mot. Exclude Happe, Ex. 1 ¶ 16, No. 16-CB-27242 [Doc. No. 292-1] ("hereinafter Happe Clobetasol Rep.").

<sup>191</sup> Happe Clomipramine Rep. ¶¶1-5

<sup>192</sup> EPPs' Mem. Supp. Mot. Exclude Happe at 3, 5, No. 16-CM-27242 [Doc. No. 231]; EPPs' Mem. Supp. Mot. Exclude Happe at 3, 5, No. 16-CB-27242 [Doc. No. 292].

<sup>193</sup> *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003).

Mr. Miller a key component of their argument on ascertainability.<sup>194</sup> EPPs are correct, however, that Dr. Happe's opinions on Mr. Miller's declaration evaluate the mechanics of the notice process, which is outside of her purview as an expert on ascertainability. It is not clear from Dr. Happe's—albeit extensive—background that she is qualified to offer a reliable opinion on the class notice process. Dr. Happe admits that she is not an expert on the legal standards for class notice and that she has never studied, researched, or investigated the ways in which notice is provided to classes that include end-payers.<sup>195</sup> Dr. Happe is not qualified to opine on the class notice process or industry standards for providing class notice.

Further, Dr. Happe's opinions on the notice process are impermissibly speculative. An expert lacks good grounds if their opinion is based not in a sound methodology, but speculation.<sup>196</sup> Dr. Happe does not provide good grounds to support her opinion that Mr. Miller's process is overbroad and that it will increase the probability that non-class members will come forward with claims, including inaccurate and duplicative claims."<sup>197</sup> Without analysis to demonstrate the likelihood that Mr. Miller's description of notice will increase the probability of inaccurate and duplicative claims, Dr. Happe's opinions are speculative. Nor does Dr. Happe provide good grounds for other speculative claims in her report, including that it is "possible that multiple entities could file claims for the same purchase[.]"<sup>198</sup> Where Dr. Happe offers affirmative opinions in her report, she must provide some kind of analysis, methodology, or basis on which she reaches those opinions. She has not done so here and, being that she does not

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<sup>194</sup> Defs.' Mem. Opp'n EPP's Mot. Exclude Happe at 10-11, No. 16-CM-27242 [Doc. No. 261]; Defs.' Mem. Opp'n EPP's Mot. Exclude Happe at 10-11, No. 16-CB-27242 [Doc. No. 324].

<sup>195</sup> Dep. Dr. Laura E. Happe, EPP's Mem. Supp. Mot. Exclude Happe, Ex. 3 at 131-132 [Doc. No. 231-3].

<sup>196</sup> *Paoli*, 35 F.3d at 742.

<sup>197</sup> Defs.' Mem. Opp'n EPP's Mot. Exclude Happe at 4 [Doc. No. 261]; Happe Clomipramine Rep. ¶ 22.

<sup>198</sup> Happe Clomipramine Rep. ¶ 142.

possess expertise in the notice process and has not studied similar issues in the past, she cannot rightfully find good grounds in her own experience to do so.

Dr. Happe is not qualified to offer her proffered opinions on notice, nor does she offer a reliable methodology to support the statements set forth in her report. The Court grants EPPs' motion to partially exclude Dr. Happe's opinions.

#### **H. Dr. Richard J. Gilbert**

Defendants offer Dr. Richard J. Gilbert as an expert on market structure, including economic issues related to the clomipramine and clobetasol cases, as well as competition in the market for both generic drugs during the relevant period. Dr. Gilbert takes issue with several arguments by EPPs' and DPPs' experts, including Dr. Lamb and Dr. Tomas G. McGuire.<sup>199</sup> Dr. Gilbert is a Distinguished Professor Emeritus of Economics at the University of California at Berkeley. Dr. Gilbert holds master's degrees in electrical engineering from Cornell University and economics from Stanford University, as well as a Ph.D. in Engineering-Economic Systems from Stanford University.<sup>200</sup> EPPs do not challenge Dr. Gilbert's qualifications.

EPPs filed a motion to exclude a portion of Dr. Gilbert's report.<sup>201</sup> In short, Dr. Gilbert provides an overview of the generic drugs market, explains the relevance of oligopolistic interdependence, explores competitive explanations for Defendants' behavior, and finds issue with multiple contentions by plaintiffs' experts. Although the bulk of Dr. Gilbert's criticisms are levied at DPPs' expert Dr. McGuire, Dr. Gilbert takes issue with EPPs' expert Dr. Lamb, arguing

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<sup>199</sup> This opinion addresses EPPs' challenges to Dr. Gilbert's opinions. A concurrent opinion will address DPPs' challenges to Dr. Gilbert.

<sup>200</sup> Gilbert Expert Report, EPPs' Mem. Supp. Mot. Exclude Gilbert, Ex. 2 ¶¶ 1-11, No. 16-CM-27242 [Doc. No 228-2] (hereinafter "Gilbert Clomipramine Report"); Gilbert Expert Report, EPPs' Mem. Supp. Mot. Exclude Gilbert, Ex. 1 ¶¶ 1-11, No. 16-CB-27242 [Doc. No 289-1] (hereinafter "Gilbert Clobetasol Report").

<sup>201</sup> See EPPs' Mot. Exclude Gilbert, No. 16-CM-27242 [Doc. No. 214]; EPPs' Mot. Exclude Gilbert, No. 16-CB-27242 [Doc. No. 272].

that Dr. Lamb does not demonstrate an understanding of normal behaviors between non-conspiring oligopolists and that Dr. Lamb incorrectly opines that Defendants' behavior can only be consistent with an illegal conspiracy. EPPs seek to exclude a subset of Gilbert's opinions as they relate to DPPs' economic expert in EPPs' action.

#### 1. Opinions on Dr. McGuire

EPPs argue that parts of Dr. Gilbert's report that solely rebut the opinions of Dr. Thomas G. McGuire, an expert for DPPs, must be excluded from EPPs' cases. In his report, Dr. Gilbert opines that Dr. McGuire cannot provide a reliable basis to show evidence of an illegal agreement between the Defendants. These criticisms constitute the majority of Dr. Gilbert's rebuttal analysis, a smaller part of which is dedicated to rebutting EPPs' expert Dr. Lamb. Thus, EPPs ask the Court to exclude Dr. Gilbert's opinions on Dr. McGuire, arguing that they are irrelevant to EPPs' cases and potentially prejudicial. Defendants counter that EPPs' objection is premature.

The controversy fails to present a *Daubert* issue. The question of admissibility of this evidence is yet to be determined, other than on its scientific bases herein. When the Court determines how and which parties will try the bellwether cases, it may then become ripe for discussion.<sup>202</sup>

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<sup>202</sup> The Court refers to DPPs' considerations in the concurrent DPP opinion. But it must be *strongly* emphasized that it is highly unusual for Defendants to presume that EPPs' and DPPs' claims on these two drugs would allow the Defense to present Dr. Gilbert's opinion on these experts ensemble without careful consideration of pretrial prejudice to any party.



## 2. Industry Background

EPPs argue that portions of Dr. Gilbert’s “industry background” section of his report are largely irrelevant and implicate market conditions that have no bearing on his analysis.<sup>203</sup> These include Dr. Gilbert’s opinions on “contractual provisions with customers,”<sup>204</sup> Dr. Gilbert’s opinions that generic prices “tend to be higher the fewer generic competitors supply the market,”<sup>205</sup> and six developments that Dr. Gilbert opines affect the generic drug industry, generally.<sup>206</sup> EPPs charge that Dr. Gilbert’s opinions on those factors are both methodologically unsound and unfit for the present cases.

A witness’s testimony must help the trier of fact to understand evidence offered to determine a fact at issue.<sup>207</sup> But where expert testimony is not “sufficiently tied to the facts of the case [such] that it will aid the jury in resolving a factual dispute,” it must be excluded.<sup>208</sup> If the court determines that substantive value of evidence is outweighed by unfair prejudice or the potential for confusion, that evidence may be excluded.<sup>209</sup>

Dr. Gilbert offers his opinions to explain economic conditions at the time of the challenged list price increases and explain key contractual provisions that influence pricing and bidding decisions. The generic drug industry is exceedingly complex, and in these cases industry

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<sup>203</sup> See Gilbert Clomipramine Rep. § IV.

<sup>204</sup> Gilbert Clomipramine Rep. ¶ 64. These include price-protection clauses, right-of-first refusal clauses, and most-favored-nation clauses.

<sup>205</sup> Gilbert Clomipramine Rep. § IV.F.

<sup>206</sup> These developments are (1) “[c]onsolidation of generic manufacturers, coupled with entry by new, smaller competitors from India and elsewhere;” (2) “[c]ongressional passage of the Generic Drug User Fee Amendments;” (3) “[t]he challenge of drug shortages;” (4) “[f]ewer expected profitable opportunities;” (5) “[i]ncreased utilization by brands of authorized generics;” and (6) “[b]uyer consolidation and pressure from customers on price.” Gilbert Clomipramine Rep. § IV.G.

<sup>207</sup> *Daubert*, 509 U.S. at 591.

<sup>208</sup> See *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985).

<sup>209</sup> Fed. R. Evid. 403.

background will be relevant to help the trier of fact industry dynamics that will bear on their understanding of key issues. EPPs do not dispute this, and in fact their experts have offered similar background to assist the trier of fact. The question is whether Dr. Gilbert's opinions on industry background are speculative, prejudicial, or unconnected to the matter at hand. They are not. For example, Dr. Gilbert describes failure-to-supply penalties in section IV.E.3 of his report.<sup>210</sup> Dr. Gilbert argues that this contractual provision came directly into play between manufacturers deciding whether to bid for new business.<sup>211</sup> According to Dr. Gilbert, record evidence indicates that at least one defendant took the manufacturer's failure-to-supply penalties into account in deciding not to submit a bid on request from Rite Aid pharmacy.<sup>212</sup>

Even where Dr. Gilbert does not directly tie background to the bellwether drugs, the evidence he presents has the potential to assist the trier of fact to understand the generic drug industry and does not risk unfair prejudice to EPPs' case. Further, Dr. Gilbert is not required to reach the question of whether any of his industry background is dispositive to prove Defendants' case.<sup>213</sup>

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<sup>210</sup> Gilbert Clomipramine Rep. § IV.E.3.

<sup>211</sup> Gilbert Clomipramine Rep. ¶ 209.

<sup>212</sup> Gilbert Clomipramine Rep. ¶215 ("There is evidence in the record illustrating manufacturers taking failure-to-supply penalties into consideration. For example, in May 2013, Sandoz considered its ability to supply when deciding how to respond to a clomipramine bid request from Rite Aid. On May 1, 2013, Taro raised its clomipramine prices and, in response, one of its customers, Rite Aid, asked whether Sandoz could take its business. Armando Kellum (Sandoz Director of Pricing) forwarded the request to his team, writing "I want to raise price and perhaps pick up share here if possible. [Lubke] try to keep Rite Aid warm and let them know we are evaluating but need to assess supply etc." In her deposition, Lubke explained that Sandoz had "very short supply" but Sandoz wanted to work with Rite Aid once it built up enough supply. Ultimately Sandoz was unable to supply Rite Aid in May 2013, but after a few months of building its inventory Sandoz won Rite Aid's business in July 2013.") (internal citations omitted).

<sup>213</sup> See *United States v. Ford*, 481 F.3d 215, 220 (3d Cir. 2007) ("[A]n expert need not have an opinion on the ultimate question to be resolved to satisfy the relevance requirement[.]") (quoting *United States v. Allen*, 390 F.3d 944, 949 (7th Cir. 2004)).

To the extent that EPPs' experts and Dr. McGuire disagree regarding the importance of his background to this case, that issue is better fit for cross-examination and goes to the weight of Dr. Gilbert's testimony.

### 3. Independent Decision-Making

EPPs argue that Dr. Gilbert's opinions are not reliable because he did not consider the meaning and implication of important evidence, including the Taro and Sandoz Deferred Prosecution Agreements ("DPAs") and the guilty plea of Armando Kellum.

The existence of some contradicting evidence is not necessarily a basis on which to exclude an expert's testimony.<sup>214</sup> The Court finds it adequate for *Daubert* purposes that Dr. Gilbert considers this evidence and concludes that there are gaps between their implications and the alleged conspiracies in these cases.<sup>215</sup> According to Dr. Gilbert, his analysis does not focus on "non-economic" evidence because it is ultimately a legal question to determine whether an agreement existed.<sup>216</sup> He indicates that his scope is limited because he has little to offer, as an economist, on conversations among competitors.

To the extent that he does not treat various record evidence of an agreement as dispositive as dispositive, his opinions go to a question that the trier of fact must ultimately consider and are ripe for questioning on cross-examination. Dr. Gilbert's opinions on these issues, however, are not unsound.

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<sup>214</sup> *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012)

<sup>215</sup> See Gilbert Clomipramine Rep. ¶¶ 19, 21-23.

<sup>216</sup> Gilbert Clomipramine Rep. ¶ 12.

#### 4. Distribution Opinion

EPPs next argue that Dr. Gilbert’s opinions on “distributions of actual prices” as evidence of competition between manufacturers in these cases lack good grounds.<sup>217</sup> EPPs argue that Dr. Gilbert forms his opinions on data indicating that the level of discounts vary across all of Defendants’ customers, but that Dr. Gilbert cites only one study to support his opinion. The study that Dr. Gilbert relies on found that powerful pharmaceutical buyers were unable to secure discounts on branded antibiotics because monopolistic conditions can inhibit larger-buyer discounts. From that, he extrapolated the opinion that “robust supplier competition” must exist in the Clobetasol and Clomipramine markets.<sup>218</sup> But Dr. Gilbert provides no empirical analysis to support his findings, according to DPPs.<sup>219</sup>

Where an expert has offered good grounds for their opinion, that court may yet “conclude that there is too great an analytical gap between the data and the opinion proffered” if the expert’s opinions do not flow from their facts presented.<sup>220</sup> Here, Dr. Gilbert has not provided good grounds for his opinion that discounts in an oligopolistic market demonstrate robust competition. The study that Dr. Gilbert cites examined the effects of monopoly branded antibiotic suppliers, but he himself has explained that the workings of an oligopoly and a monopoly are structurally different.<sup>221</sup> To demonstrate that discounts are evidence of competition, Dr. Gilbert need provide some analysis of discounts in an oligopolistic market—

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<sup>217</sup> Gilbert Clomipramine Rep. § IV.H.

<sup>218</sup> EPPs’ Mem. Supp. Mot. Exclude Gilbert at 22-24 [Doc. No. 228].

<sup>219</sup> *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

<sup>220</sup> *See In re TMI Litig.*, 193 F.3d 613, 682 (3d Cir 1999), *as amended*, 199 F.3d 158 (3d Cir. 2009).

<sup>221</sup> Gilbert Clomipramine Rep. ¶¶131, 143.

whether through his own model or by relying on other evidence that describes conditions in an oligopoly.

EPPs' motion to exclude section IV.H of Dr. Gilbert's report is granted.

#### **IV. Conclusion**

EPPs' motions to partially exclude the opinions of Dr. James Hughes, Dr. Erin Trish, and Dr. Laura Happe are **GRANTED**.

EPPS' motion to partially exclude Dr. Gilbert's opinions is **GRANTED** in part to exclude the opinions set forth in section IV.H of his report.

Defendants' motion to exclude the opinions of Dr. James McClave, Dr. Russell Lamb, Ms. Laura Craft, and Mr. Eric Miller are **DENIED**.

An order will be entered